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APPLICATION NUMBER: ***60/421,024***
FILING DATE: ***October 24, 2002***
RELATED PCT APPLICATION NUMBER: *PCT/US03/23839*

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EL737584692US

INVENTOR(S)

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☐ *Additional inventors are being named on the____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

SINGLE USE SYRINGE FOR RECONSTITUTION PROCEDURES

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages*	10	☐ CD(s), Number	
☒ Drawing(s) *Number of Sheets*	8	☒ Other (specify)	Exhibit A ((31 sheets)
☐ Application Data Sheet. See 37 CFR 1.76			

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐	Applicant claims small entity status. See 37 CFR 1.27.	FILING FEE AMOUNT ($)
☐	A check or money order is enclosed to cover the filing fees	
☒	The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 02-1666	$160.00
☐	Payment by credit card. Form PTO-2038 is attached.	

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No

☐ Yes, the name of the U S Government agency and the Government contract number are _____

Respectfully submitted,

SIGNATURE Jeanne P. Lukasavage

Date Oct. 24, 2002

TYPED or PRINTED NAME Jeanne P. Lukasavage

REGISTRATION NO. *(if appropriate)* 45,172

Docket Number: P-5874

TELEPHONE 201-847-6797

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C.

SINGLE USE SYRINGE FOR RECONSTITUTION PROCEDURES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is related to U.S. Application Serial No. 10/254,924 filed September 25, 2002, which is hereby incorporated by reference and attached as Exhibit A.

BACKGROUND OF THE INVENTION

[0002] The present invention is related to single use syringes and more particularly to auto-disable single use syringes for use in reconstitution procedures.

[0003] In the United States and throughout the world, the multiple use of hypodermic syringe products that are intended for single use only is instrumental in drug abuse and more particularly in the transfer of diseases. Intravenous drug users who routinely share and reuse syringes are a high risk group with respect to the bloodborne pathogens including HIV and AIDS. Also the effects of multiple use are a major concern in under-developed countries where repeated use of syringe products may be responsible for the spread of many diseases. Reuse of single use hypodermic syringe assemblies is instrumental in the spread of drug abuse even in the absence of infection or disease.

[0004] Many attempts have been made to remedy this problem, Some of these attempts have required a specific act to destroy the syringe after use either by using a destructive device or providing a syringe assembly with frangible zones so that the syringe could be rendered inoperable by application of force. Other attempts have involved the inclusion of structure which would allow the destruction or defeating of the syringe function through a conscious act by the syringe user. Although many of these devices work quite well, they do require the specific intent of the user followed by the actual act to destroy or render the syringe inoperable.

[0005] Other prior art syringes are auto-disable syringes. Such syringes automatically disable after an injection stroke is made. Thus, these syringes cannot be used for procedures that require more than a single aspiration and injection strokes. For example, such syringes cannot be used for reconstitution or other applications which require more than a single stroke of the plunger rod.

[0006] Syringes are available in many different sizes, and have plunger rods that are commensurate in size with the syringe barrels in which they are used. This generally necessitates the use of a different size locking element for each size syringe.

SUMMARY OF THE INVENTION

[0007] The invention relates to a syringe assembly including a locking element capable of locking a plunger rod with respect to a syringe barrel. The assembly includes a syringe barrel, a plunger rod assembly and a locking element. The syringe barrel includes an inside surface defining a chamber, a ring, an open end, and a distal end. The plunger rod assembly includes an elongate body portion and a stopper. The locking element is slidably positioned within the chamber of the syringe barrel, engaging the inside surface thereof such that the locking element is substantially immovable in the direction of the open end of the syringe. It is also engageable with the plunger rod assembly such that the plunger rod assembly can be moved proximally and distally to reconstitute a drug and then the plunger rod assembly and locking element can be moved distally together toward the distal end of the syringe barrel. In a preferred embodiment, the plunger rod assembly can initially be moved proximally with respect to the locking element to aspirate fluid into the syringe barrel. The body portion of the plunger rod includes one or more axially extending recesses. Each recess is defined by a pair of converging surfaces. At least one of the recesses is defined by surfaces that converge along a line that is displaced from the longitudinal axis of the plunger rod. The locking element is positioned within the recess and is engageable with one or both converging surfaces. It accordingly is movable in the distal direction with the plunger assembly.

[0008] Fig. 1 is an exploded, perspective view of a single use syringe assembly according to the invention.

[0009] Fig. 1A is an exploded cross-sectional view showing the syringe assembly of FIG. 1.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Fig. 2 is a perspective view of a locking element.

[0011] Fig. 3 is a side elevation view of the locking element.

[0012] Fig. 4 is a cross-sectional view of the locking element taken along line 4-4 of Fig. 3.

[0013] Fig. 5 is a cross-sectional view of the locking element taken along line 5-5 of Fig. 3.

[0014] Fig. 6 is an end view of the locking element.

[0015] Fig. 7 is a top perspective view of the syringe assembly as packaged.

[0016] Fig. 7A is a cross-sectional view of the syringe assembly as shown in Fig. 7.

[0017] Fig. 8 is a top perspective view of the syringe assembly with the plunger rod assembly in position following the first aspiration.

[0018] Fig. 8A is a cross-sectional view of the syringe assembly as shown in Fig. 8.

[0019] Fig. 9 is a top perspective view of the syringe assembly with the plunger rod assembly in position following the first injection.

[0020] Fig. 9A is a cross-sectional view of the syringe assembly as shown in Fig. 9.

[0021] Fig. 10 is a top perspective view of the syringe assembly with the plunger rod assembly in position following the second aspiration.

[0022] Fig. 10A is a cross-sectional view of the syringe assembly as shown in Fig. 10.

[0023] Fig. 11 is a top perspective view of the syringe assembly with the plunger rod assembly in position following the second injection.

[0024] Fig. 11A is a cross-sectional view of the syringe assembly as shown in Fig. 11.

DETAILED DESCRIPTION

[0025] Referring first to Figs. 1, and 7-11, a single use syringe assembly 20 includes a barrel 22 having an inside surface 24 defining a chamber 26 for retaining fluid. The inside surface 24 of the barrel further defines an annular ring 27 projecting therefrom. The barrel 22 includes an open proximal end 28 and a distal end 30 having a collar 32 defining a passageway 34 therethrough in communication with the chamber. A needle cannula (not shown) projects outwardly from the distal barrel end and is in fluid communication with the chamber. The collar 32 of the barrel as shown is a non-standard collar and therefore cannot be used with a standard needle cannula, e.g., a standard luer locking cannula. Therefore, reuse of the needle or the syringe is difficult. It will be appreciated that the invention could be applied to syringe assemblies having permanently affixed needles or needle/hub assemblies, or fixed or removable blunt cannulas, or standard luer locking assemblies. While intended for reconstitution of vaccines, the syringe assembly can be used for general curative purposes or other purposes.

[0026] As used in the preceding paragraph and hereafter, the term "distal end" refers to the end furthest from the person holding the syringe assembly. The term "proximal end" refers to the end closest to the holder of the syringe assembly. In the preferred embodiment, the proximal end of the barrel 22 includes a flange 36 to facilitate handling and positioning of

the syringe assembly and to maintain the relative position of the barrel with respect to the plunger rod during filling and medication administration.

[0027] A plunger rod assembly 38 used in the syringe assembly 20 includes an elongate body portion 40 including a plurality of elongate recesses 42 running substantially parallel to the longitudinal axis of rotation thereof. The distal end of the elongate body portion includes an integral stopper 44. A disc-shaped flange 46 is provided at the proximal end of the plunger rod for allowing the user to apply the force necessary to move the plunger rod with respect to the barrel.

[0028] The elongate body portion 40 includes a pair of discs 48, 50 intermediate the proximal and distal ends thereof. The sections between the relatively proximal disc 50 and the flange 46 and the relatively distal disc 48 and the stopper 44 include radially extending walls 51, 52, both of which preferably traverse the longitudinal axis of rotation of the plunger rod assembly 38. Additional pairs of distal walls 53 resembling fins extend perpendicularly from both sides of one wall 52 of the radially extending walls in the section between the distal disc 48 and stopper 44. In this embodiment, as shown in the FIGS., there are four pairs of distal walls 53 including wall faces 55, 57. The first pair 53a of distal walls extend perpendicularly from the upper side of wall 52 and the second pair 53b extend from the lower side of wall 52. The third and fourth pairs are mirror images of the first and second extending from the wall 52 on the side opposite from the first and second pairs beyond wall 51.

[0029] In a preferred embodiment, each of the distal walls 53 is substantially parallel to each other. The areas between each of the pairs of walls could be filled in to provide additional rigidity if necessary. Teeth 54 are formed on selected surfaces of the walls 53. In a preferred embodiment, each of the first pair 53a of distal walls defines a pair teeth 54a. Each of the second pair 53b of distal walls defines a plurality of teeth 54b. Each tooth 54a, 54b includes a distally facing surface or shoulder 56. The wall surfaces 55, 57 including the teeth converge along an imaginary line that runs substantially parallel to the longitudinal axis of the plunger rod assembly, but radially displaced therefrom. As shown in the drawings, the surfaces 55, 57 do not necessarily adjoin each other. The wall surfaces define recesses 42 for positioning of a locking element 60. While four recesses are provided, a greater or lesser number may be employed. It will be appreciated that the recesses 42 can be formed by surfaces that actually meet along the line of convergence. It will further be appreciated that while the plunger rod assembly as shown and described herein is of integral construction, it may in fact be comprised of two or more separate elements. The stopper may, for example,

be a separate component made from a material that is different from the material comprising the remainder of the plunger rod assembly. Preferably, the syringe barrel is comprised of polypropylene, and contains an internal lubricant and the plunger rod assembly is comprised of polyethylene.

[0030] According to one embodiment of the invention, the diameter of the barrel is that of a standard 10 ml 2 piece syringe, at least about 13.5 mm (0.53 inch). For delivery of smaller doses, for example, 2ml, 3ml, 5ml, the length of the syringe is reduced from the length of the standard 10 ml syringe to the length required to deliver the smaller dose. Thus, the bulk of the syringe is reduced, while the pressure can be more easily controlled due to the greater diameter of the barrel. For delivery of larger doses, for example, 10ml, the diameter of a standard 20ml barrel, or larger barrel, can be used, while, again reducing the length of the syringe to accommodate the smaller dose. The reduction in the bulk of the syringe reduces the packaging, which is advantageous in syringes having an integral cannula. The diameter of the plunger is also increased, increasing the pressure it exerts. This improves the reconstitution process.

[0031] The locking element 60 is positioned within the barrel 22 and within one of the elongate recesses 42 defined by the pairs of distal walls 53. As shown in the drawings, the locking element 60 is placed within the first pair of walls 53a which each define a pair of teeth. When the locking element 60 is placed within either of the first pair of distal walls 53a, the syringe may be used for reconstitution procedures, or any other procedure requiring two strokes of the plunger. Alternatively, the locking element 60 may be placed within the second pair of distal walls 53b. When placed in this location, the plunger is only capable of a single injection stroke, and therefore, the syringe cannot be used for procedures requiring more than one aspiration and injection stroke. The recess 42 acts as a pathway for longitudinal motion of the locking element relative to the plunger rod assembly. Since the recesses are displaced from the longitudinal axis of the plunger rod assembly, the same size locking element can be used that is employed in a smaller syringe. In the smaller syringe, the locking element would be positioned in a recess adjoining the longitudinal axis or at least closer to this axis than in the syringe disclosed herein. U.S. Patent Nos. 4,961,728 and 5,989,219 disclose the placement of a locking element at or near the longitudinal axis. A syringe as disclosed in these patents could be provided for administering doses of about 0.5ml. The invention allows the same size locking element to be used in such very small syringes as well as those exceeding five milliliters.

[0032] The locking element 60, as best shown in FIGS. 2-6, includes a generally V-shaped body portion 61 comprising first and second radially extending walls 62, 64 joined along a longitudinal axis. The walls 62, 64 preferably form an angle of greater than ninety degrees, and preferably about one hundred degrees. A first leg 66 extends proximally from the first wall and a second leg 68 extends proximally from the second wall 64. The legs flare outwardly with respect to the V-shaped body portion 61, as best shown in Fig. 2. The legs 66, 68 are preferably substantially longer than the length of the body portion 61. For example, in a locking element having an overall length of about seventeen millimeters, the legs 66, 68 may be about ten millimeters in length.

[0033] Each of the legs 66, 68 includes a proximal end portion 70, 72 that is angled towards one of the walls 53 of the plunger rod assembly. They further include inner and outer edges. (The terms "inner" and "outer" are relative terms as used herein.) The inner edges thereof are substantially adjacent to each other, separated by a longitudinal gap 74. Barbs 76, 78 are integral with the outer edges of the first and second legs. The barbs face proximally, and are preferably located slightly distally of the angled end portions 70, 72. The barbs may be different in appearance from those shown in the drawings so long as they are capable of engaging the inside surface 24 of the syringe barrel to prevent proximal movement of the locking element.

[0034] A second pair of legs extends distally from the V-shaped body portion 61. One of these legs 80 extends from the first wall 62 and the other 82 from the second wall 64. Barbs 84, 86 extend proximally from the distal ends of the legs 80, 82. The barbs are formed on the outer edges of the distally extending legs. Each leg further includes a cutting edge 87 capable of penetrating the stopper 44.

[0035] The locking element is preferably formed from a thin sheet of metal such as stainless steel. The thickness in a preferred embodiment thereof is about 0.20 mm. The dimensions of the locking element are selected in accordance with the barrels and plunger rod assemblies with which it is to be used. The angle formed between the two halves of the locking element, as shown in Fig. 2, is preferably greater than ninety degrees, and preferably about one hundred degrees. When placed in one of the recesses 42 in the plunger rod assembly, the locking element will accordingly exert a force against the two of the converging wall surfaces 55, 57 that define the recess. The cutting edges 87 are preferably formed by providing bevels on one side of the substrate from which the locking element is constructed. It will be appreciated that the substrate could be ground on both sides thereof to form cutting

edges for disabling the stopper 44. Alternatively, barbs (not shown) or other cutting members can be provided on the locking element for piercing the stopper.

[0036] The syringe assembly is easily constructed from the component parts thereof and packaged as shown in FIGS. 7 and 7A. First, the locking element 60 is positioned in one of recesses 42 in the plunger rod assembly such that the angled end portions of the legs 66, 68 adjoin the relatively distal disk 48. As shown in FIGS. 7 and 7A, the locking element 60 is positioned in the recess formed by the first pair of distal walls 53a. In this position, the syringe may be used for a reconstitution process as will be illustrated. The legs 66, 68 and spring member extend proximally, and the barbs 76, 78, 84, 86 are angled proximally with respect to the plunger rod assembly. The plunger rod/locking element assembly is then inserted into the barrel 22 through the proximal end thereof.

[0037] As the assembly is moved distally within the barrel, the angular orientation of the barbs allows them to slide along while engaging inside surface 24 of the barrel. The locking element moves distally with the plunger rod due to the engagement of the ends of legs 66, 68 with the disc 48. The gap 74 is maintained between the legs 66, 68 even after installation of the locking element. The maintenance of the gap and the relatively long lengths of the legs, which act as cantilever springs, provide a relatively reduced force on the barrel and facilitate use and installation. The plunger rod/locking element assembly is moved distally until the stopper engages the end wall of the barrel and the distal portion of the locking element 60, including the cutting edge 87 and barbs 84 abut the ring 27 as shown in Figs. 7 and 7A. The syringe is then ready for use or storage. A needle cover can be mounted to the distal end of the barrel to protect the needle cannula. The cover is removed prior to use.

[0038] In use, plunger rod assembly 38 is retracted from the position shown in Figs. 7 and 7A to the position shown in Figs. 8 and 8A in order to perform the first aspiration, drawing reconstitution fluid through needle cannula and into chamber 26 of barrel 22. The plunger is retracted back so that the stopper abuts the ring 27. Locking element 60 remains stationary during such retraction, and the plunger rod assembly is moved proximally with respect to both barrel 22 and the locking element. This is due to the engagement of barbs 76, 78, 84, 86 with inside surface 24 of the barrel. The barbs are preferably made from a harder material than the barrel, which enhances their ability to resist proximal movement. Angled ends 70, 72 of legs 66, 68 of the locking element ride over the distal tooth 54a of the plunger rod assembly during retraction thereof. The stopper abuts the ring 27 before the locking

element rides over the proximal tooth 53a as shown in FIGS. 8 and 8A. The teeth 53a are spaced apart to allow the locking clip 60 to pass over only the distal detent during the first aspiration while allowing the proper quantity of reconstitution fluid to be withdrawn into the syringe. For example, about 3.0-3.4ml of reconstitution fluid is required for a 3ml dose. Thus, retraction of the plunger rod assembly 38 during aspiration is limited by the locking element 60 and the ring 27.

[0039] The reconstitution fluid may now be injected into a lyophilized drug container. During the injection of the reconstitution fluid, the plunger is moved distally until the stopper bottoms out. This empties the contents of the syringe. The locking element 60 remains nearly motionless, but may be slightly moved by the distal detent during the injection of the reconstitution fluid as shown in FIGS. 9 and 9A.

[0040] The reconstituted drug may now be drawn into the chamber of the syringe. During the aspiration of the reconstituted drug, the locking element 60 passes over the proximal tooth 53a as shown in FIGS. 10 and 10A. The plunger is withdrawn proximally until the stopper abuts the ring 27. The distal end of the locking element 60 now abuts the proximal side of the stopper. The user feels the engagement of the locking element and stopper and the ring and stopper. Cutting edges 87 do not penetrate the stopper as a result of the forces exerted during normal use. As the locking element cannot be moved proximally, further retraction of the plunger rod assembly is resisted. The amount of fluid that can be drawn into chamber 26 is accordingly limited by the distance between the proximal surface of the stopper and the disc 48 as well as the length of the locking element and the location of the ring 27. It will be appreciated that the distance between the stopper and the relatively distal disc 48, the length of the locking element 60, the location of the ring 27 and the distance between each of the pair of teeth 54a can be chosen to meet the needs of particular applications. The proximal end portions of legs 66, 68 of the locking element adjoin the end of the distal tooth 54a when the plunger rod assembly is retracted to the position shown in Figs. 8 and 8A. As discussed above, the locking element is substantially immovable in the proximal direction within the barrel due to the engagement of the barbs with the inside surface of the barrel 22.

[0041] Once the reconstituted fluid has been drawn into the barrel, the needle cannula can be removed from the fluid source and used for injection. During the injection of a patient, plunger assembly 38 and locking element both move distally from the positions shown in Figs. 10 and 10A to the positions shown in Figs. 11 and 11A. In Figs. 11 and 11A,

stopper 44 again adjoins or engages the end wall of barrel 22. Locking element 60 remains positioned on the distal side of the distal tooth 54a. Both plunger rod assembly 38 and the locking element are substantially immovable from their positions. Syringe assembly 20 accordingly cannot be reused. Should a person use extraordinary force in an attempt to retract the plunger rod assembly from the position shown in Figs. 11 and 11A, the cutting edges 87 at the distal end of the locking element will penetrate the stopper, rendering it unusable. Disabling of the stopper preferably occurs when the force exerted is approximately sufficient to dislodge the locking element in the proximal direction, or a lesser force. As discussed above, simple engagement of the cutting edges and stopper should not compromise the integrity of the stopper.

[0042] An additional tamper-resistance feature is comprised of notches 89 in the plunger rod assembly. If the plunger rod assembly is twisted forcefully, it will break prior to disablement of locking element 60.

[0043] If the locking element is positioned within the recess defined by the second pair of distal walls 53b, the syringe would only be usable for a single aspiration and injection stroke. The syringe would operate in the same way as fully disclosed in U.S. Patent Application Serial No. 10/254,924 filed September 25, 2002, which is attached hereto as Exhibit A.

[0044] Thus, the same plunger assembly 38 can be used for single aspiration/injection procedures or procedures requiring two aspirations and injections. Alternatively, the plunger assembly 38 may be provided with distal walls 43 that each only include a pair of teeth 54. In such a device, the locking element 60 may be placed in any recess in order to perform a reconstitution procedure.

[0045] The syringe barrel of the present invention may be constructed of a wide variety of rigid materials with thermoplastic materials such as polypropylene and polyethylene being preferred. Similarly, thermoplastic materials such as polypropylene, polyethylene and polystyrene are preferred for the plunger rod and integral stopper. A wide variety of materials such as natural rubber, synthetic rubber, thermoplastic elastomers and combinations thereof are suitable for the stopper if the stopper is manufactured as a separate component. The choice of stopper material will depend on compatibility with the medication being used.

[0046] As previously recited, it is preferable that the locking element be fabricated from a material which is harder than the barrel so that the locking barbs may effectively

engage the barrel. Resilient spring like properties are also desirable along with low cost, dimensionally consistent fabrication. With this in mind, sheet metal is the preferred material for the locking element with stainless steel being preferred for medical applications. Although the locking element of the preferred embodiment is fabricated from a single sheet, it is within the purview of the instant invention to include locking elements made of other forms and/or containing multiple parts. Locking elements having structures other than that shown and described herein could also be successfully employed. One such locking element is disclosed in U.S. Patent No. 5,989,219, the disclosure of which is incorporated by reference herein. The distal end of the locking element disclosed in the patent could be provided with a cutting edge similar to those described above. Alternatively, barbs (not shown) could be provided at the distal end of the locking element for rendering the stopper unusable.

[0047] The syringe barrel employed in accordance with the invention may have a varying wall thickness along its length. The portion of the barrel used for containing medication could be relatively thin and resilient to ensure proper sealing with the stopper. The remainder of the barrel could be relatively thick and less resilient such that it would tend to crack if squeezed by pliers or another device used for attempted tampering. Sufficient barrel crystallinity is desirable in the area of the locking element to cause this area to crack upon deformation of the syringe barrel to an extent that would permit retraction of the plunger rod assembly with the locking element.

[0048] Thus, it can be seen that the present invention provides a simple, reliable, easily fabricated, single use syringe which becomes inoperable or incapable of further use without any additional act on the part of the user. It further allows the use of a locking element of the same size that is used on smaller or larger syringes.

[0049] Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention.

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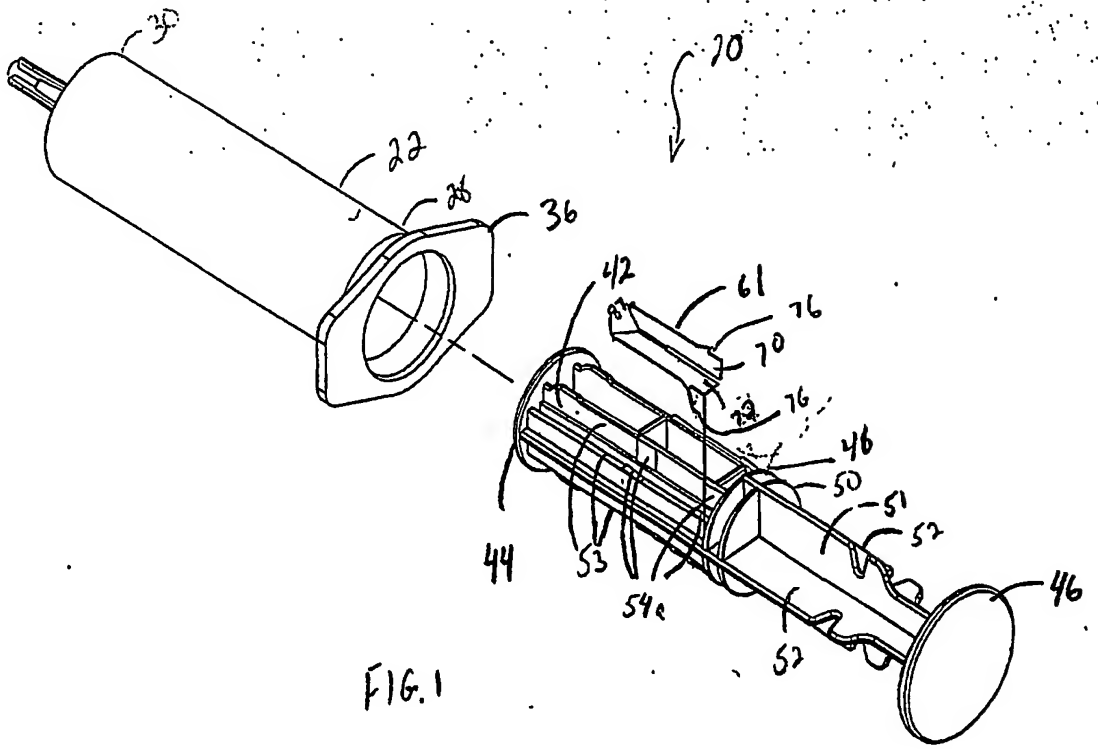
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FIG. 1

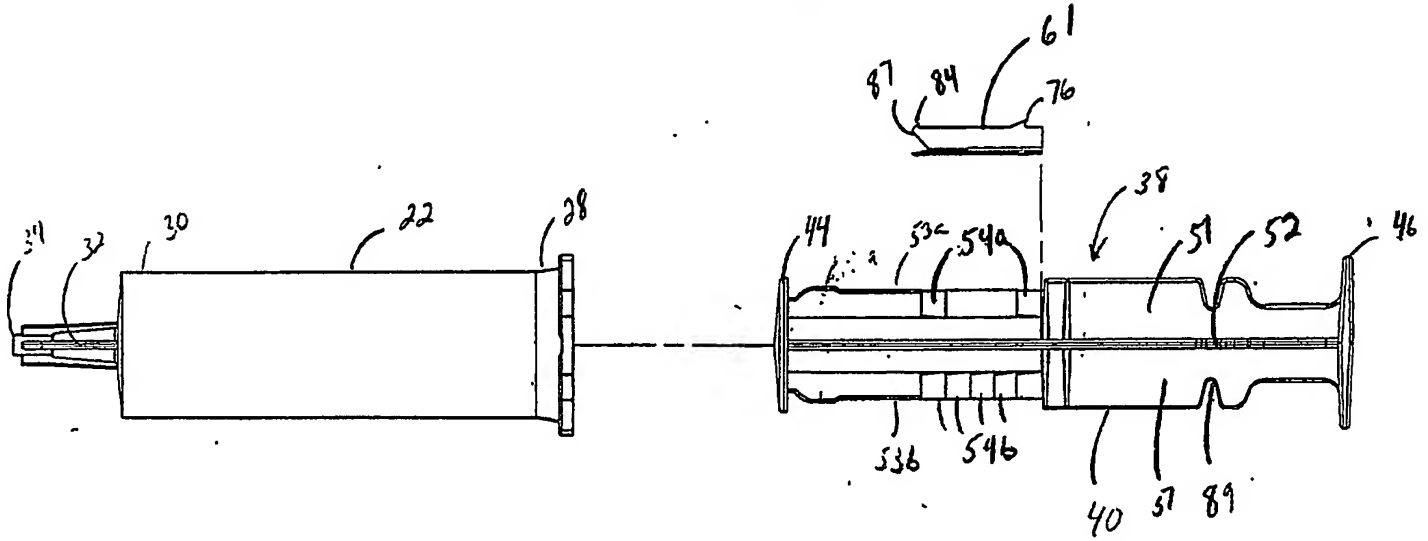
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FIG 1A

FIG. 2

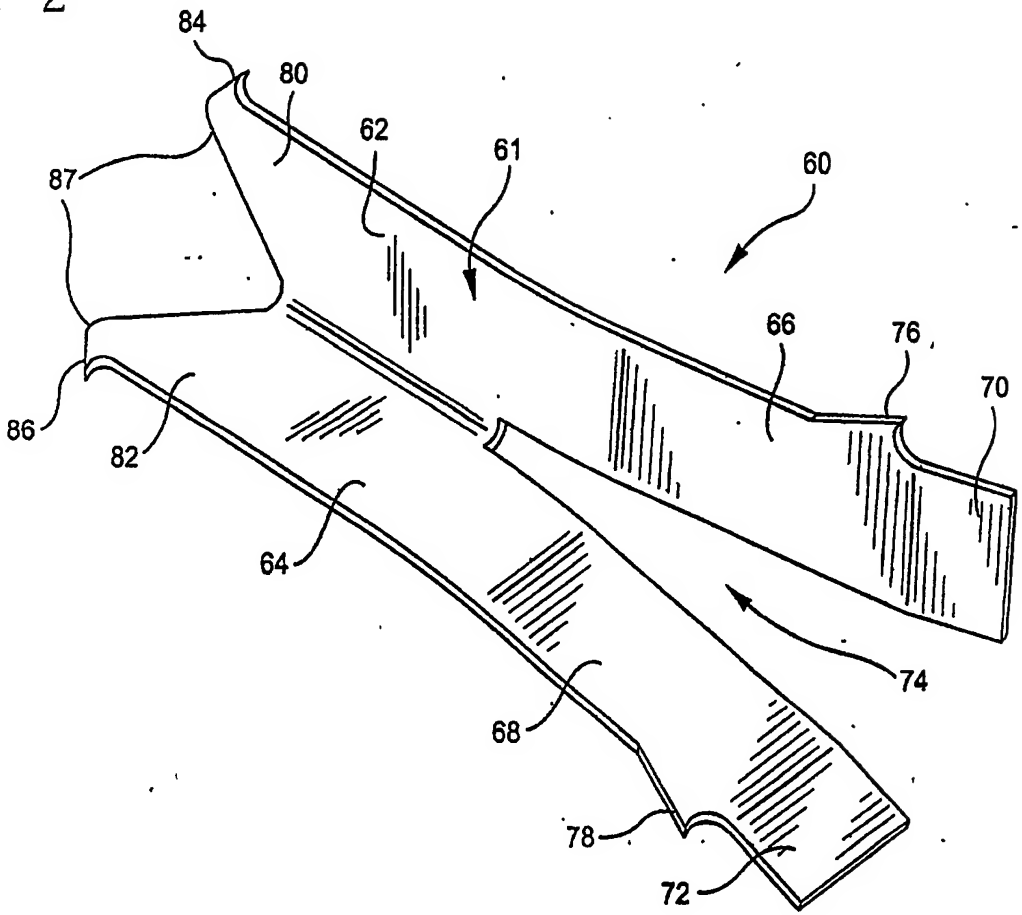


FIG. 3

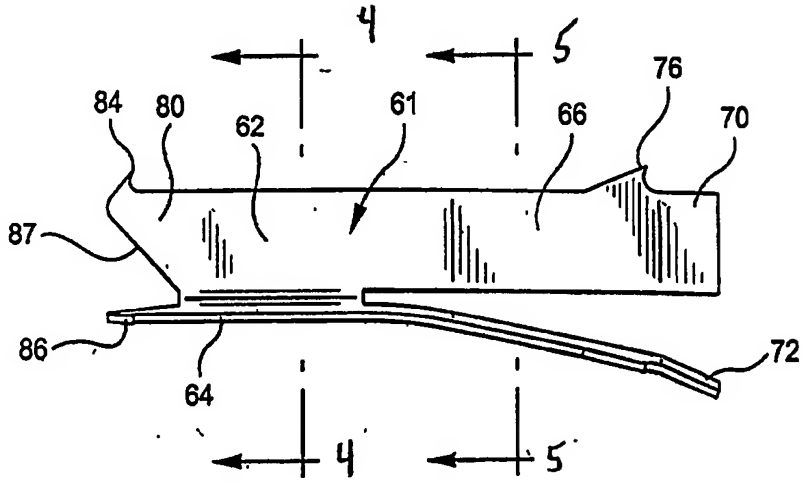


FIG. 4

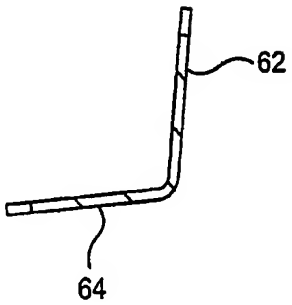


FIG. 5

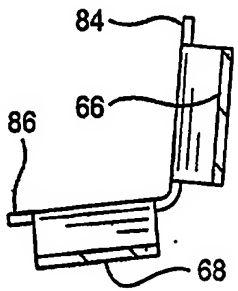
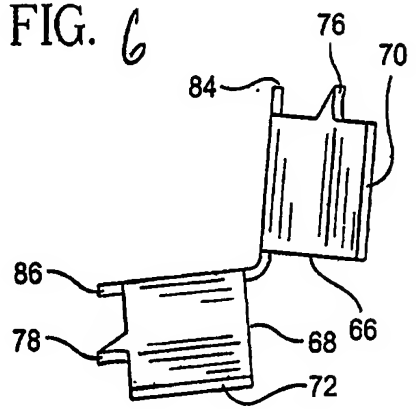


FIG. 6



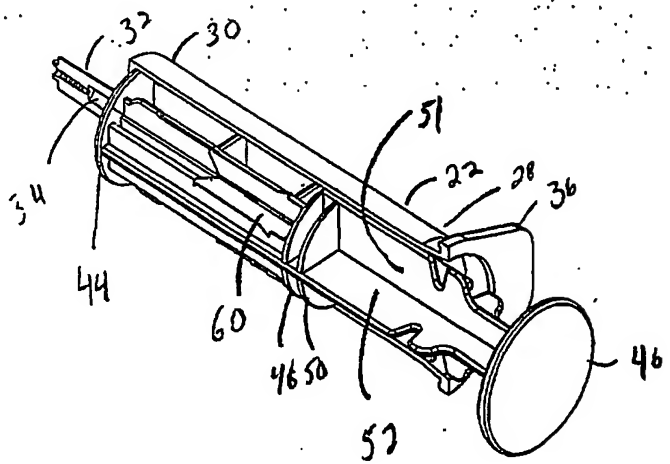

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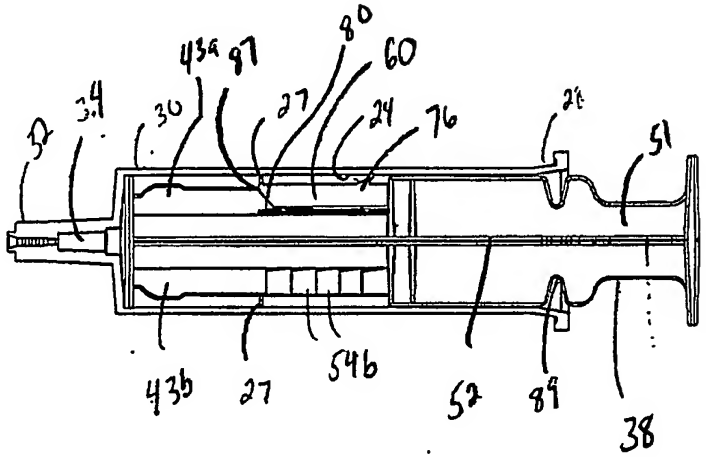
FIG. 7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76
28
51
43b
27
54b
52
89
38

FIG. 7A

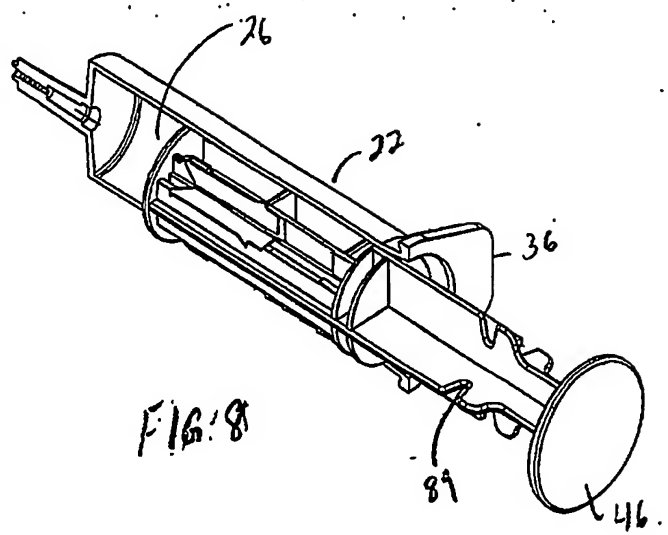

FIG. 8

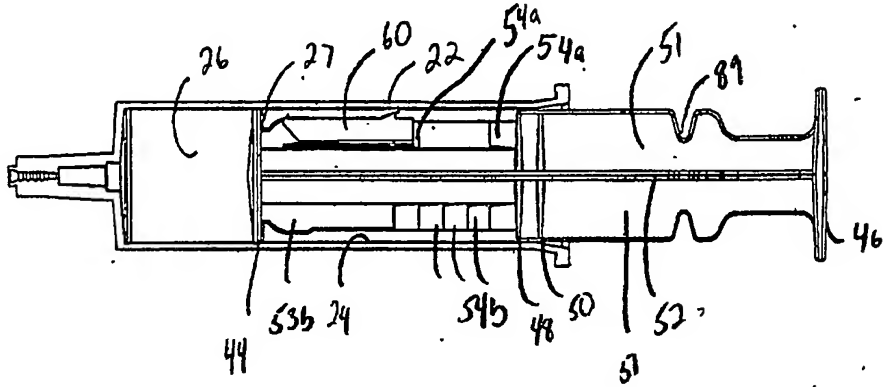

FIG 8A

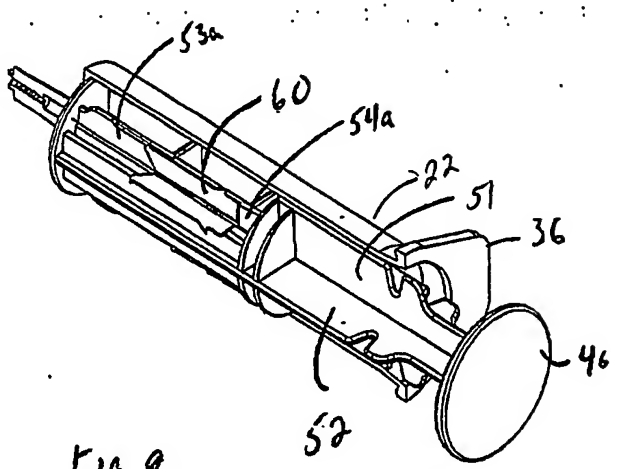

FIG 9

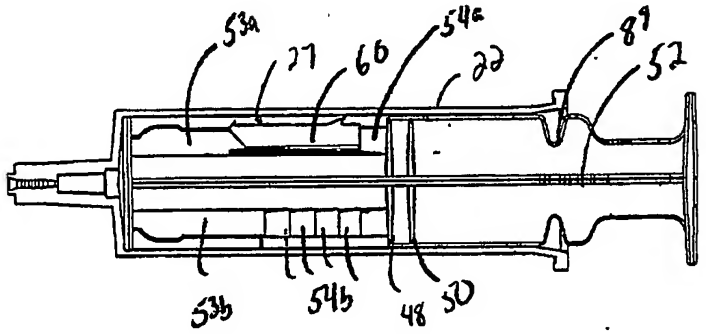

FIG. 9A

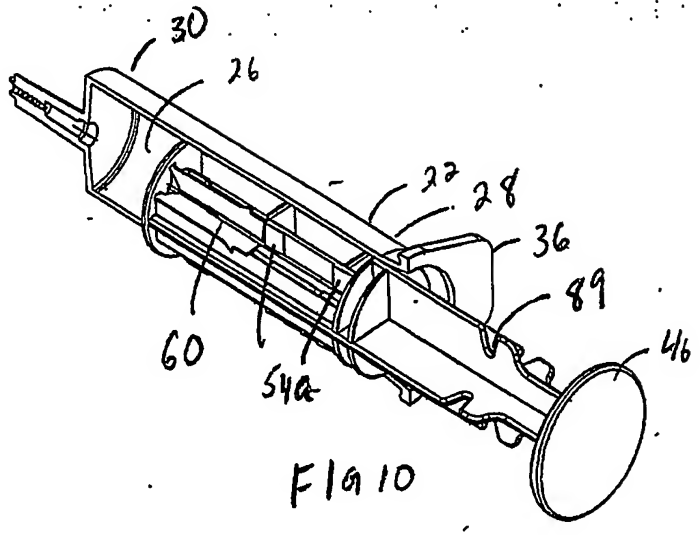

FIG 10

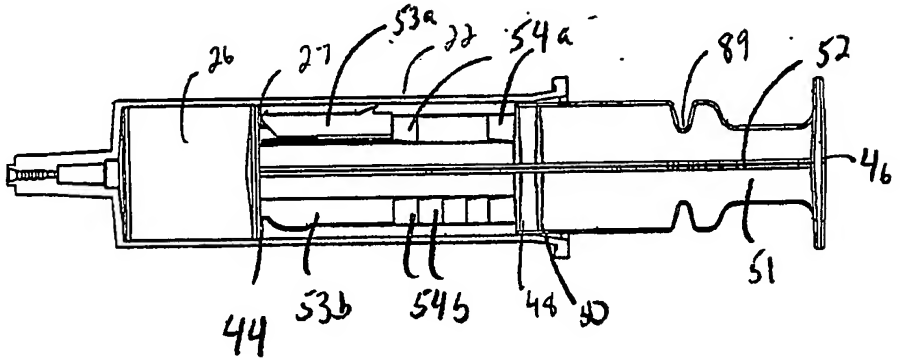

FIG 10A

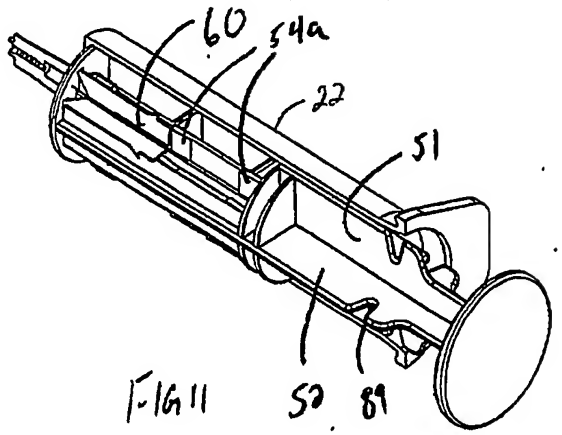

FIG 11

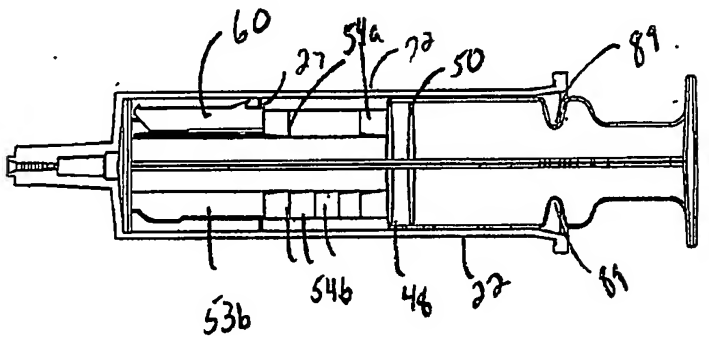

FIG. 11A

EXHIBIT A

P-5755

Docket Number: P-5755

SINGLE USE SYRINGE AND PLUNGER ROD LOCKING DEVICE THEREFOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to single use syringes and locking devices for locking the plunger assemblies of such syringes.

2. Brief Description of the Related Art

In the United States and throughout the world the multiple use of hypodermic syringe products that are intended for single use only is instrumental in drug abuse and more particularly in the transfer of contagious diseases. Intravenous drug users who routinely share and reuse syringes are a high risk group with respect to the AIDS virus. Also, the effects of multiple use are a major concern in third world countries where repeated use of syringe products may be responsible for the spread of many diseases. Reuse of single use hypodermic syringe assemblies is also instrumental in the spread of drug abuse even in the absence of infection or disease.

Many attempts have been made to remedy this problem. Some of these attempts have required a specific act to destroy the syringe after use either by using a destructive device or providing a syringe assembly with frangible zones so that the syringe could be rendered inoperable by the application of force. Other attempts have involved the inclusion of structure which would allow the destruction or defeating of the syringe function through a conscious act by the syringe user. Although many of these devices work quite well, they do require the specific intent of the user followed by the actual act to destroy or render the syringe inoperable. None of these devices is effective with a user having the specific intent to reuse the hypodermic syringe.

Single use hypodermic syringes that become inoperative or incapable of further use automatically without any additional act on the part of the user have been developed. One such syringe is disclosed in U.S. Patent No. 4,961,728. The syringe disclosed in this patent includes a locking element positioned in the syringe barrel. The locking element includes proximally and outwardly facing barbs that engage the

inner surface of the syringe barrel and an inwardly facing driving edge adapted to interact with the plunger rod to move the locking element along the barrel as the stopper is advanced. The plunger rod includes a ledge positioned at a distance from the proximal side of a support wall that approximates the length of the locking element. The driving edge of the locking element engages the ledge, thereby ensuring that the locking element moves distally with the plunger rod and stopper. A syringe including a similar locking element is disclosed in U.S. Patent No. 5,989,219.

U.S. Patent Nos. 5,021,047, 5,062,833 and 5,562,623 disclose single use syringes having plunger rods that have teeth or ridges and locking elements that engage the teeth or ridges. The locking elements of these syringes also include outwardly extending teeth or prongs that engage the inside surface of the syringe barrel. The plunger rods of these syringes can be retracted to draw fluid into the syringe barrel while the locking elements remain stationary. Distal movement of the plunger rods causes the fluid to be expelled, the locking elements moving distally with the plunger rods and substantially preventing further plunger rod retraction.

Syringes are available in many different sizes, and have plunger rods that are commensurate in size with the syringe barrels in which they are used. This generally necessitates the use of a different size locking element for each size syringe.

SUMMARY OF THE INVENTION

The invention relates to a syringe assembly including a locking element capable of locking a plunger rod with respect to a syringe barrel. The assembly includes a syringe barrel, a plunger rod assembly and a locking element. The syringe barrel includes an inside surface defining a chamber, an open end, and a distal end. The plunger rod assembly includes an elongate body portion and a stopper. The locking element is slidably positioned within the chamber of the syringe barrel, engaging the inside surface thereof such that the locking element is substantially immovable in the direction of the open end of the syringe. It is also engageable with the plunger rod assembly such that the plunger rod assembly and locking element can be moved distally together toward the distal end of the syringe barrel. In a preferred embodiment, the plunger rod assembly can initially be moved proximally with respect to the locking element to aspirate fluid into the syringe barrel. The body portion of

the plunger rod includes one or more axially extending recesses. Each recess is defined by a pair of converging surfaces. At least one of the recesses is defined by surfaces that converge along a line that is displaced from the longitudinal axis of the plunger rod. The locking element is positioned within the recess and is engageable with one or both converging surfaces. It accordingly is movable in the distal direction with the plunger assembly.

A plunger rod assembly is further provided. The plunger rod assembly includes an elongate body and a stopper mounted near the distal end of the body. The body includes a longitudinal axis that is co-linear with the longitudinal axis of rotation of the body. An axially extending recess is defined by the body, and includes a pair of converging surfaces that converge along a line that is generally parallel to but displaced from the longitudinal axis. The stopper is positioned distal to the recess. In a preferred embodiment, the elongate body includes radially extending walls that converge at or near the longitudinal axis and one or more additional walls extending from the radially extending walls. The additional walls define one or more surfaces of the recess.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded, perspective view showing a single use syringe assembly according to the invention;

Fig. 2 is a top perspective view showing the syringe assembly as provided to a user;

Fig. 3 is a top perspective view thereof showing the syringe assembly following retraction of the plunger rod assembly thereof;

Fig. 4 is a top perspective view of the syringe assembly with the plunger rod assembly in a locked position following an injection;

Fig. 5 is a top perspective view thereof showing the operation of a tamper-resistance feature of the syringe assembly upon attempted retraction of the plunger rod assembly from the locked position of Fig. 4;

Fig. 6 is a sectional view thereof showing the plunger rod assembly in a position prior to initial retraction;

Fig. 6A is an enlarged sectional view of the distal end thereof;

Fig. 7 is a sectional view thereof showing the plunger rod assembly as retracted by the user to draw fluid into the syringe barrel;

Fig. 7A is an enlarged sectional view showing the distal end of the plunger rod assembly;

Fig. 8 is sectional view thereof following the injection stroke;

Fig. 8A is an enlarged sectional view of the distal end thereof;

Fig. 9 is an enlarged sectional view thereof showing the operation of a tamper-resistance feature upon attempted retraction of the plunger rod assembly from the position shown in Fig. 8;

Fig. 10 is a sectional view taken along line 10-10 of Fig. 6;

Fig. 11 is a perspective view of a plunger rod assembly in accordance with a preferred embodiment of the invention;

Fig. 12 is a perspective view of a locking element;

Fig. 13 is another perspective view of the locking element;

Fig. 14 is an enlarged elevation view of the distal end thereof;

Fig. 15 is a side elevation view thereof;

Fig. 16 is a sectional view thereof taken along line 16-16 of Fig. 15;

Fig. 17 is a sectional view thereof taken along line 17-17 of Fig. 15; and

Fig. 18 is an end view thereof.

DETAILED DESCRIPTION OF THE INVENTION

There is shown in the drawings and will be described in detail herein a preferred embodiment of the invention with the understanding that the present disclosure is to be considered as exemplary of the principles of the invention and is not intended to limit the invention to the embodiment illustrated.

Referring first to Figs. 1-9, a single use syringe assembly 20 includes a barrel 22 having an inside surface 24 defining a chamber 26 for retaining fluid. The barrel 22 includes an open end 28 and a distal end 30 having a passageway 32 therethrough

in communication with the chamber. A needle cannula 34 projects outwardly from the distal barrel end. The needle cannula has a lumen (not shown) therethrough in fluid communication with the passageway and a sharpened distal tip. The syringe assembly of the present invention is shown with a needle cannula assembly including a hub 35 that is removably attached to the distal end of the barrel. It will be appreciated that the invention could be applied to syringe assemblies having permanently affixed needle/hub assemblies, or fixed or removable blunt cannulas. While intended for reconstitution of vaccines, the syringe assembly could be used for general curative purposes or other purposes.

As used in the preceding paragraph and hereafter, the term "distal end" refers to the end furthest from the person holding the syringe assembly. The term "proximal end" refers to the end closest to the holder of the syringe assembly. In the preferred embodiment, the proximal end of the barrel 22 includes a flange 36 to facilitate handling and positioning of the syringe assembly and to maintain the relative position of the barrel with respect to the plunger rod during filling and medication administration.

A plunger rod assembly 38 used in the syringe assembly 20 includes an elongate body portion 40 including a plurality of elongate recesses 42 running substantially parallel to the longitudinal axis of rotation thereof. The distal end of the elongate body portion includes an integral stopper 44. A disc-shaped flange 46 is provided at the proximal end of the plunger rod for allowing the user to apply the force necessary to move the plunger rod with respect to the barrel. The elongate body portion 40 includes a pair of discs 48, 50 intermediate the proximal and distal ends thereof. The sections between the relatively proximal disc 50 and the flange 46 and the relatively distal disc 48 and the stopper 44 include radially extending walls 51, 52, both of which traverse the longitudinal axis of rotation of the plunger rod assembly 38. Additional walls 53 that resemble fins extend perpendicularly from both sides of one 52 of the radially extending walls in the section between the distal disc 48 and stopper. In this preferred embodiment, the walls 53 are substantially parallel to each other. The areas between walls could be filled in to provide additional rigidity if necessary. Ratchet-like teeth 54 are formed on selected surfaces of the walls 53, as best shown in Figs. 10 and 11. Each tooth 54 includes a distally facing surface or

shoulder 56. The wall surfaces 55, 57 including the teeth converge along an imaginary line that runs substantially parallel to the longitudinal axis of the plunger rod assembly, but radially displaced therefrom. As shown in the drawings, the surfaces 55, 57 do not necessarily adjoin each other. They together define recesses 42 for positioning of a locking element 60. While four recesses are provided, a greater or lesser number may be employed. It will be appreciated that the recesses 42 can be formed by surfaces that actually meet along the line of convergence. It will further be appreciated that while the plunger rod assembly as shown and described herein is of integral construction, it may in fact be comprised of two or more separate elements. The stopper may, for example, be a separate component made from a material that is different from the material comprising the remainder of the plunger rod assembly. In this preferred embodiment, the syringe barrel is comprised of polypropylene, and contains an internal lubricant, and the plunger rod assembly is comprised of polyethylene.

The locking element 60 is positioned within the barrel 22 and within one of the elongate recesses 42 defined by the additional walls 53. The recess 42 acts as a pathway for longitudinal motion of the locking element relative to the plunger rod assembly. As the recesses are displaced from the longitudinal axis of the plunger rod assembly, the same size locking element can be used that is employed in a smaller syringe. In the smaller syringe, the locking element would be positioned in a recess adjoining the longitudinal axis or at least closer to this axis than in the syringe disclosed herein. U.S. Patent Nos. 4,961,728 and 5,989,219 disclose the placement of a locking element at or near the longitudinal axis. A syringe as disclosed in these patents could be provided for administering doses of about 0.5ml. The invention allows the same size locking element to be used in such very small syringes as well as those exceeding five milliliters.

The locking element 60, as best shown in Figs. 12-18, includes a generally V-shaped body portion 61 comprising first and second radially extending walls 62, 64 joined along a longitudinal axis. The walls 62, 64 preferably form an angle of greater than ninety degrees, and preferably about one hundred degrees. A first leg 66 extends proximally from the first wall and a second leg 68 extends proximally from the second wall 64. The legs flare outwardly with respect to the V-shaped body portion

61, as best shown in Fig. 15. The legs 66, 68 are preferably substantially longer than the length of the body portion 61. In a locking element having an overall length of about seventeen millimeters, the legs 66, 68 may be about ten millimeters in length.

Each of the legs 66, 68 includes a proximal end portion 70, 72 that is angled towards one of the walls 53 of the plunger rod assembly. They further include inner and outer edges. (The terms "inner" and "outer" are relative terms as used herein.) The inner edges thereof are substantially adjacent to each other, separated by a longitudinal gap 74. Barbs 76, 78 are integral with the outer edges of the first and second legs. The barbs face proximally, and are preferably located slightly distally of the angled end portions 70, 72. The barbs may be different in appearance from those shown in the drawings so long as they are capable of engaging the inside surface 24 of the syringe barrel to prevent proximal movement of the locking element.

A second pair of legs extends distally from the V-shaped body portion 61. One of these legs 80 extends from the first wall 62 and the other 82 from the second wall 64. Barbs 84, 86 extend proximally from the distal ends of the legs 80, 82. The barbs are formed on the outer edges of the distally extending legs. Each leg further includes a cutting edge 87 capable of penetrating the stopper 44.

The locking element is preferably formed from a thin sheet of metal such as stainless steel. The thickness in a preferred embodiment thereof is about 0.20 mm. The dimensions of the locking element are selected in accordance with the barrels and plunger rod assemblies with which it is to be used. The angle formed between the two halves of the locking element, as shown in Fig. 16, is preferably greater than ninety degrees, and preferably about one hundred degrees. When placed in one of the recesses 42 in the plunger rod assembly, the locking element will accordingly exert a force against the two of the converging wall surfaces 55, 57 that define the recess. The cutting edges 87 are formed by providing bevels on one side of the substrate from which the locking element is constructed. It will be appreciated that the substrate could be ground on both sides thereof to form cutting edges for disabling the stopper 44. Alternatively, barbs (not shown) or other cutting members can be provided on the locking element for piercing the stopper. Fig. 9 shows the penetration of the stopper by the cutting edges that will occur should one attempt to reuse the syringe following an injection.

The syringe assembly is easily constructed from the component parts thereof. The locking element 60 is positioned in one of the recesses 42 in the plunger rod assembly such that the angled end portions of the legs 66, 68 adjoin the relatively distal disk 48, as shown in Figs. 2 and 6. Alternatively, the end portions of the legs can initially abut selected teeth 54 should a smaller dosage be required. The legs 66, 68 and spring member extend proximally, and the barbs 76, 78, 84, 86 are angled proximally with respect to the plunger rod assembly. The plunger rod/locking element assembly is then inserted into the barrel 22 through the proximal end thereof. As the assembly is moved distally within the barrel, the angular orientation of the barbs allows them to slide along while engaging the inside surface 24 of the barrel. The locking element moves distally with the plunger rod due to the engagement of the ends of the legs 66, 68 with the disc 48. The gap 74 is maintained between the legs 66, 68 even after installation of the locking element. The maintenance of the gap and the relatively long lengths of the legs, which act as cantilever springs, provide a relatively reduced force on the barrel and facilitate use and installation. The plunger rod/locking element assembly is moved distally until the stopper engages the end wall of the barrel as shown in Figs. 2 and 6. It is then ready for use or storage. A needle cover 90 can be mounted to the distal end of the barrel to protect the needle cannula. The cover is removed prior to use.

In use, the plunger rod assembly 38 is retracted from the position shown in Figs. 2 and 6 to the position shown in Figs. 3 and 7 in order to draw fluid through the needle cannula 34 and passageway 32 and into the chamber 26 of the barrel 22. The locking element 60 remains stationary during such retraction, and the plunger rod assembly is moved proximally with respect to both the barrel 22 and the locking element. This is due to the engagement of the barbs 76, 78, 84, 86 with the inside surface 24 of the barrel. The barbs are preferably made from a harder material than the barrel, which enhances their ability to resist proximal movement. The angled ends 70, 72 of the legs 66, 68 of the locking element ride over the teeth 54 of the plunger rod assembly during retraction thereof. The user may feel and/or hear the movement of the legs over the teeth.

Retraction of the plunger rod assembly 38 is limited by the locking element. As shown in Figs. 7 and 7A, the proximal surface of the stopper 44 engages the distal

end of the locking element 60. The user can feel this engagement. The cutting edges 87 do not penetrate the stopper as a result of the forces exerted during normal use. As the locking element cannot be moved proximally, further retraction of the plunger rod assembly is not possible. The amount of fluid that can be drawn into the chamber 26 is accordingly limited by the distance between the proximal surface of the stopper and the disc 48 as well as the length of the locking element. It will be appreciated that the distance between the stopper and the relatively distal disc 48 and the length of the locking element 54 can be chosen to meet the needs of particular applications.

The proximal end portions of the legs 66, 68 of the locking element adjoin the end of a relatively distal tooth 54 when the plunger rod assembly is retracted to the position shown in Figs. 7 and 7A. The distance between this end of the tooth 54 and the distal end surface of the relatively distal disc 48, being substantially the same as the distance between the distal end of the locking element and the proximal end portions of the legs, causes the locking element to be substantially immovable with respect to the plunger rod assembly. As discussed above, the locking element is substantially immovable in the proximal direction within the barrel due to the engagement of the barbs with the inside surface of the barrel 22. (Though not preferred, the syringe can be provided to the end user as a prefilled syringe, in which case retraction of the plunger rod assembly would not be possible.)

Once the fluid has been drawn into the barrel from a vial or other fluid source, the needle cannula can be removed from the fluid source and used for injection. During the injection of a patient, the plunger assembly 38 and locking element both move distally from the positions shown in Figs. 7 and 7A to the positions shown in Figs. 8 and 8A. In Figs. 8 and 8A, the stopper 44 again adjoins or engages the end wall of the barrel 22. The locking element 54 remains positioned between the disc 48 and most distal ratchet tooth 54. Both the plunger rod assembly 38 and the locking element are substantially immovable from their positions. The syringe assembly 20 accordingly cannot be reused. Should a person use extraordinary force in an attempt to retract the plunger rod assembly from the position shown in Figs. 8 and 8A, the cutting edges 87 at the distal end of the locking element will penetrate the stopper, rendering it unusable, as shown in Fig. 9. Disabling of the stopper preferably occurs when the force exerted is sufficient to dislodge the locking element in the proximal

direction, or a slightly lesser force. As discussed above, simple engagement of the cutting edges and stopper should not compromise the integrity of the stopper.

An additional tamper-resistance feature is comprised of notches 89 in the plunger rod assembly. If the plunger rod assembly is twisted forcefully, it will break prior to disablement of the locking element 60.

The syringe barrel of the present invention may be constructed of a wide variety of rigid materials with thermoplastic materials such as polypropylene and polyethylene being preferred. Similarly, thermoplastic materials such as polypropylene, polyethylene and polystyrene are preferred for the plunger rod and integral stopper. A wide variety of materials such as natural rubber, synthetic rubber and thermoplastic elastomers are suitable for the stopper if the stopper is manufactured as a separate component. The choice of stopper material will depend on compatibility with the medication being used.

As previously recited, it is preferable that the locking element be fabricated from a material which is harder than the barrel so that the locking barbs may effectively engage the barrel. Resilient spring like properties are also desirable along with low cost, dimensionally consistent fabrication. With this in mind, sheet metal is the preferred material for the locking element with stainless steel being preferred for medical applications. Although the locking element of the preferred embodiment is fabricated from a single sheet, it is within the purview of the instant invention to include locking elements made of other forms and/or containing multiple parts. Locking elements having structures other than that shown and described herein could also be successfully employed. One such locking element is disclosed in U.S. Patent No. 5,989,219, the disclosure of which is incorporated by reference herein. The distal end of the locking element disclosed in the patent could be provided with a cutting edge similar to those described above. Alternatively, barbs (not shown) could be provided at the distal end of the locking element for rendering the stopper unusable.

The syringe barrel employed in accordance with the invention may have a varying wall thickness along its length. The portion of the barrel used for containing medication could be relatively thin and resilient to ensure proper sealing with the stopper. The remainder of the barrel could be relatively thick and non-resilient such

that it would tend to crack if squeezed by pliers or another device used for attempted tampering. Sufficient barrel crystallinity is desirable in the area of the locking element to cause this area to crack upon deformation of the syringe barrel to an extent that would permit retraction of the plunger rod assembly with the locking element.

Thus, it can be seen that the present invention provides a simple, reliable, easily fabricated, single use syringe which becomes inoperable or incapable of further use without any additional act on the part of the user. It further allows the use of a locking element of the same size that is used on smaller or larger syringes.

What is claimed is:

1. A syringe assembly comprising:

a syringe barrel having an inside surface defining a chamber, an open end, and a distal end;

a plunger rod assembly extending within said syringe barrel and including an elongate body portion having a longitudinal axis, a stopper connected to said elongate body portion, and an axially extending recess, said recess being bounded by a pair of surfaces and being radially displaced from the longitudinal axis of said elongate body portion, and

a locking element slidably positioned within said chamber and extending within said recess, said locking element engaging said inside surface of said syringe barrel such that said locking element is substantially immovable in the direction of the open end of said syringe barrel, said locking element further being engageable with at least one of said surfaces of said plunger rod assembly such that said plunger rod assembly and locking element can be moved distally together toward the distal end of said syringe barrel with said locking element being maintained in said recess and substantially displaced from the longitudinal axis of said plunger rod assembly.

2. The syringe assembly of claim 1 wherein said locking element is comprised of an integral, resilient metal structure, said locking element being positioned such that said plunger rod assembly can be moved proximally with respect to said locking element.

3. The syringe assembly of claim 1 wherein said locking element includes one or more proximally extending barbs engaging said inside surface of said syringe barrel, and said locking element and stopper are positioned such that said plunger rod assembly can be moved proximally with respect to said locking element.

4. The syringe assembly of claim 3 wherein said locking element includes a body portion having a distal end and proximal end, said body portion of said locking element being generally V-shaped and engageable with each of said pair of surfaces bounding said recess.

5. The syringe assembly of claim 4 including a first pair of legs extending from and deflectable with respect to said proximal end of said body portion, said legs engaging said plunger rod assembly.

6. The syringe assembly of claim 5 including a first proximally extending barb adjacent said distal end of said body portion and a second proximally extending barb extending from at least one of said legs, said first and second barbs engaging said inside surface of said syringe barrel.

7. The syringe assembly of claim 1 wherein said elongate body portion of said plunger rod assembly includes a plurality of radially extending walls that converge near said longitudinal axis and a first additional wall extending from one of said radially extending walls in a non-radial direction, said first additional wall defining one of said surfaces bounding said recess.

8. The syringe assembly of claim 7 including a second additional wall extending from one of said radially extending walls, said second additional wall defining one of said surfaces bounding said recess.

9. The syringe assembly of claim 8 wherein said second additional wall is substantially parallel to said first additional wall.

10. The syringe assembly of claim 1 wherein said elongate body portion of said plunger rod assembly includes a first wall proximal to said stopper and a plurality of second walls projecting from a first side of first wall, two of said second walls defining said surfaces of said recess.

11. The syringe assembly of claim 10 wherein at least one of said surfaces of said recess includes a plurality of abutments for engaging said locking element.

12. The syringe assembly of claim 10 wherein said second walls extend substantially perpendicularly with respect to said first wall.

13. The syringe assembly of claim 10 wherein said second walls extend from two sides of said first wall and define a plurality of recesses, each of said recesses capable of receiving said locking element.

14. The syringe assembly of claim 10 wherein said locking element includes a generally V-shaped body portion engageable with each of said pair of surfaces bounding said recess.

15. The syringe assembly of claim 12 wherein said locking element includes a generally V-shaped body portion engageable with each of said pair of surfaces bounding said recess.

16. A plunger rod assembly for a syringe, comprising:

an elongate body having a longitudinal axis and a proximal end and a distal end, said longitudinal axis being substantially co-linear with the longitudinal axis of rotation of said elongate body;

a stopper mounted near the distal end of said elongate body, and

an axially extending recess defined by said elongate body including a pair of converging surfaces that converge along a line that is generally parallel to said longitudinal axis but displaced radially therefrom, said stopper being positioned distal to said recess.

17. The plunger rod assembly of claim 16 including a locking element having a generally V-shaped body portion extending within said recess and engageable with said converging surfaces.

18. The plunger rod assembly of claim 16 wherein said elongate body includes a first wall and a plurality of second walls projecting from a first side of said first wall, two of said second walls defining said converging surfaces of said recess.

19. The plunger rod assembly of claim 17 wherein said second walls are substantially parallel to each other.

20. The plunger rod assembly of claim 19 wherein said second walls extend from two sides of said first wall and define a plurality of recesses bounded by converging surfaces.

21. A syringe assembly comprising:

a syringe barrel having an inside surface defining a chamber, an open end and a distal end;

a plunger rod assembly extending within said syringe barrel and including an elongate body having a longitudinal axis of rotation and a stopper mounted to said elongate body;

a locking element having a generally V-shaped body portion and including means for engaging said inside surface of said syringe barrel and means for engaging said plunger rod assembly such that said locking element is substantially immovable in the direction of said open end and movable with the plunger rod towards said distal end, and

means for maintaining said locking element radially displaced at a substantial distance from said longitudinal axis of said plunger rod assembly.

22. The syringe assembly of claim 21 wherein said means for maintaining includes an elongate, axially extending recess in said plunger rod assembly, said locking element being positioned in said recess such that said generally V-shaped body portion is positioned with a pointed end oriented towards said longitudinal axis and a pair of free ends adjoining said inside surface of said syringe barrel, said pointed end being a substantial distance from said longitudinal axis.

23. The syringe assembly of claim 22 wherein said plunger rod assembly includes a plurality of substantially parallel walls, portions of two of said walls defining said recess.

ABSTRACT OF THE DISCLOSURE

A single use syringe and a plunger rod assembly for such a syringe are provided. The syringe includes features that cause the plunger rod to be locked with respect to the syringe barrel upon completion of an injection stroke. The locking device may include barbs for engaging the syringe barrel and relatively long, proximally extending legs. The legs include barbs for engaging the syringe barrel and end portions for engaging the plunger rod. The plunger rod assembly includes a recess defined by converging surfaces, the recess being displaced from the longitudinal axis thereof. A locking element that fits a smaller syringe can thereby be used in a larger syringe as well.

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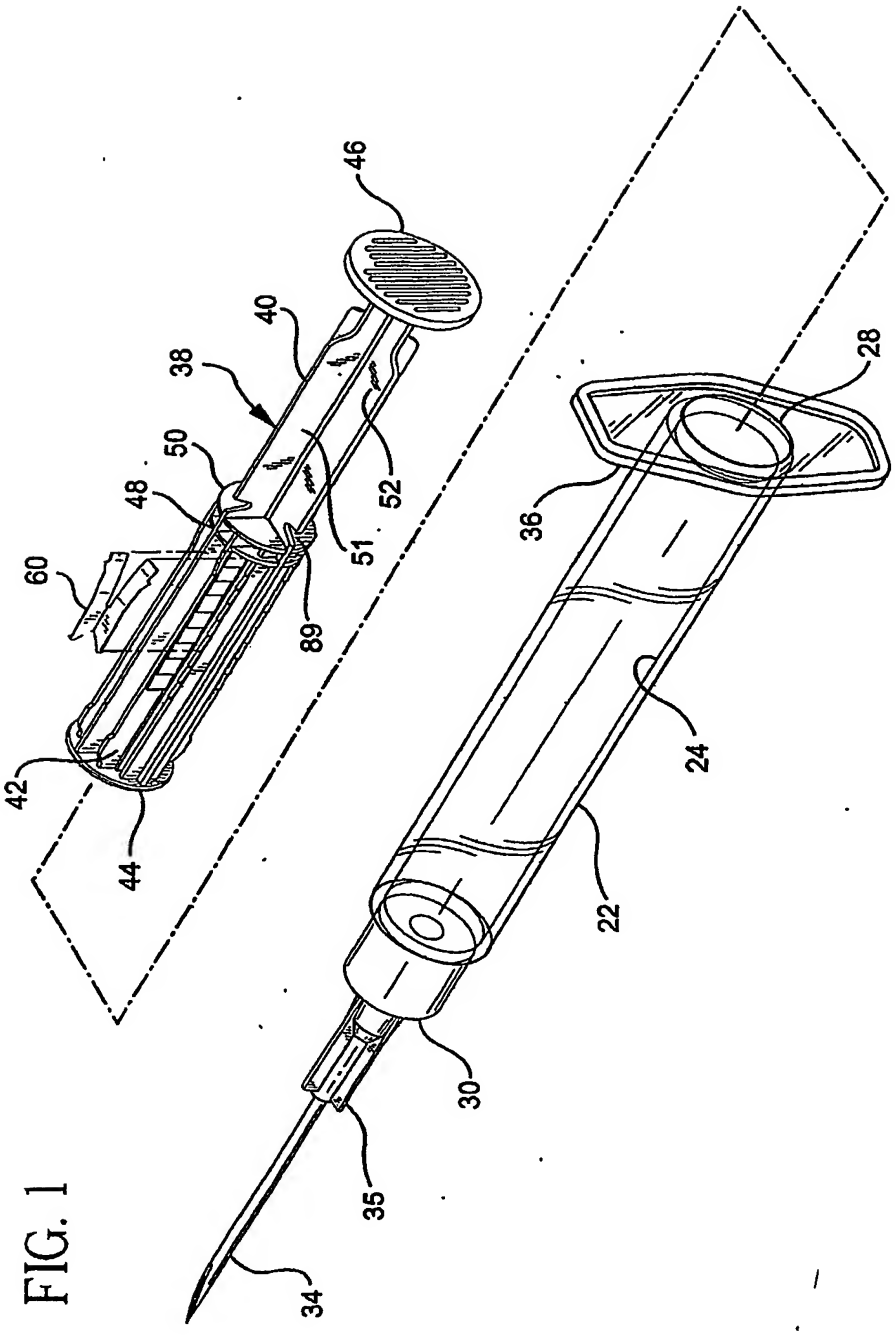

FIG. 1

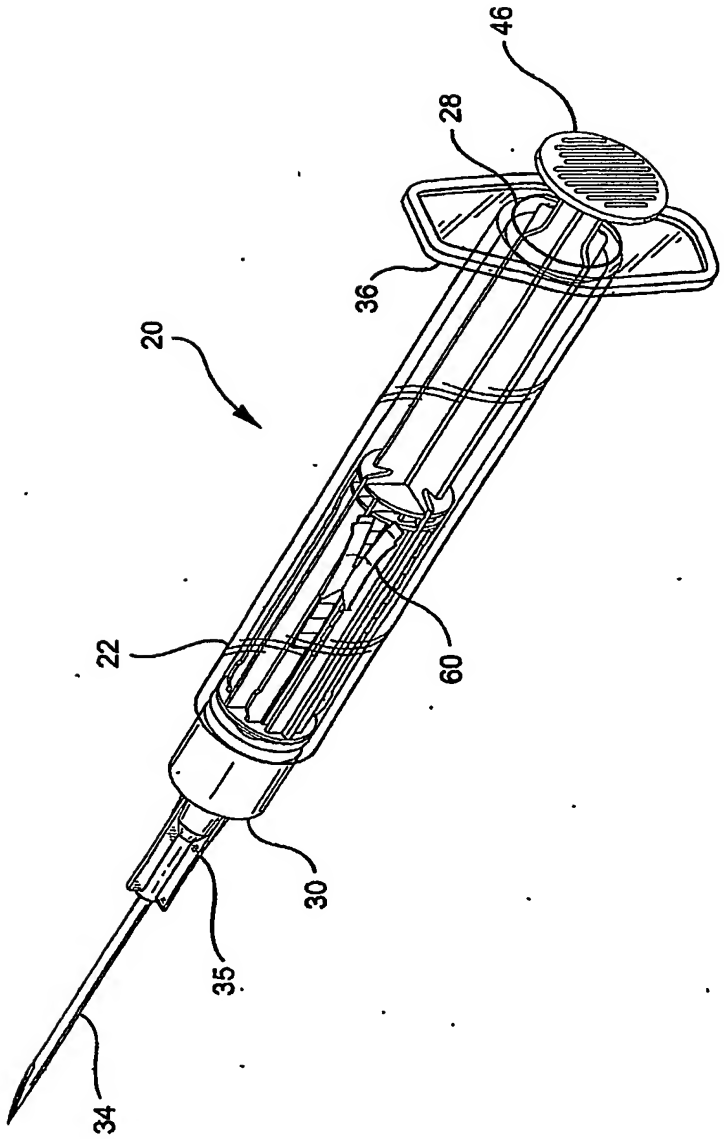

FIG. 2

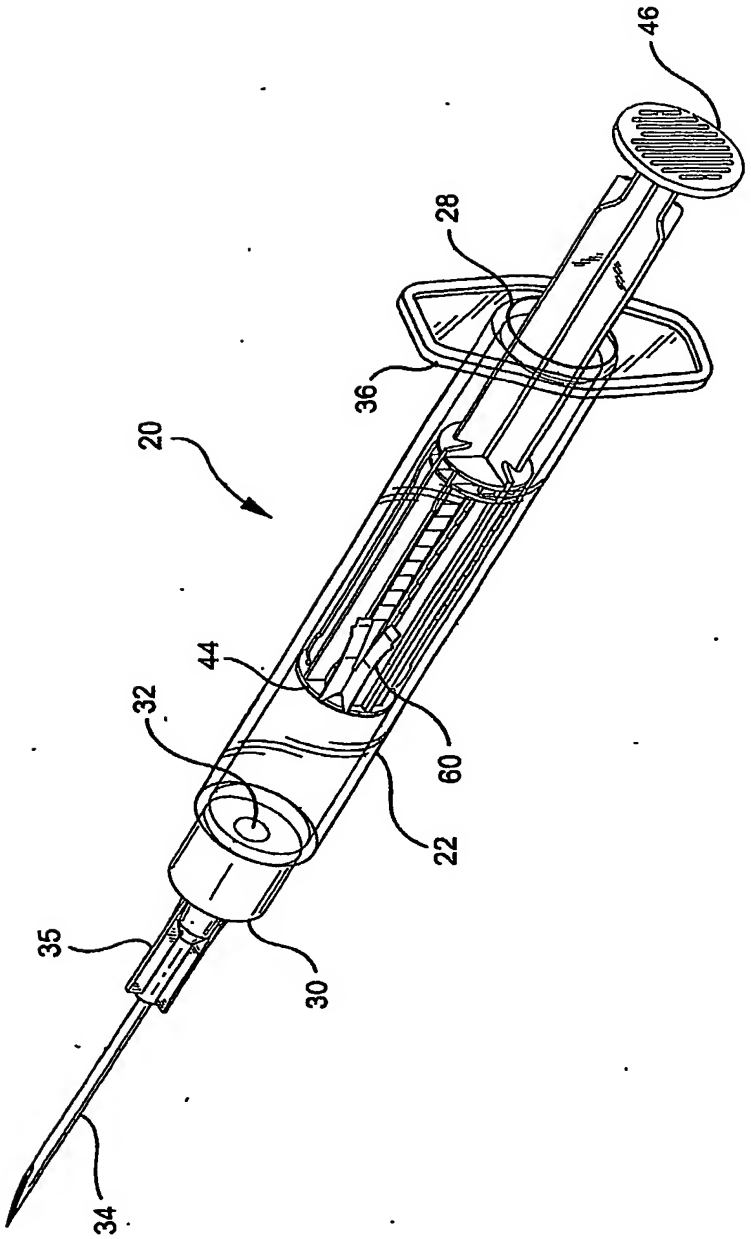

FIG. 3

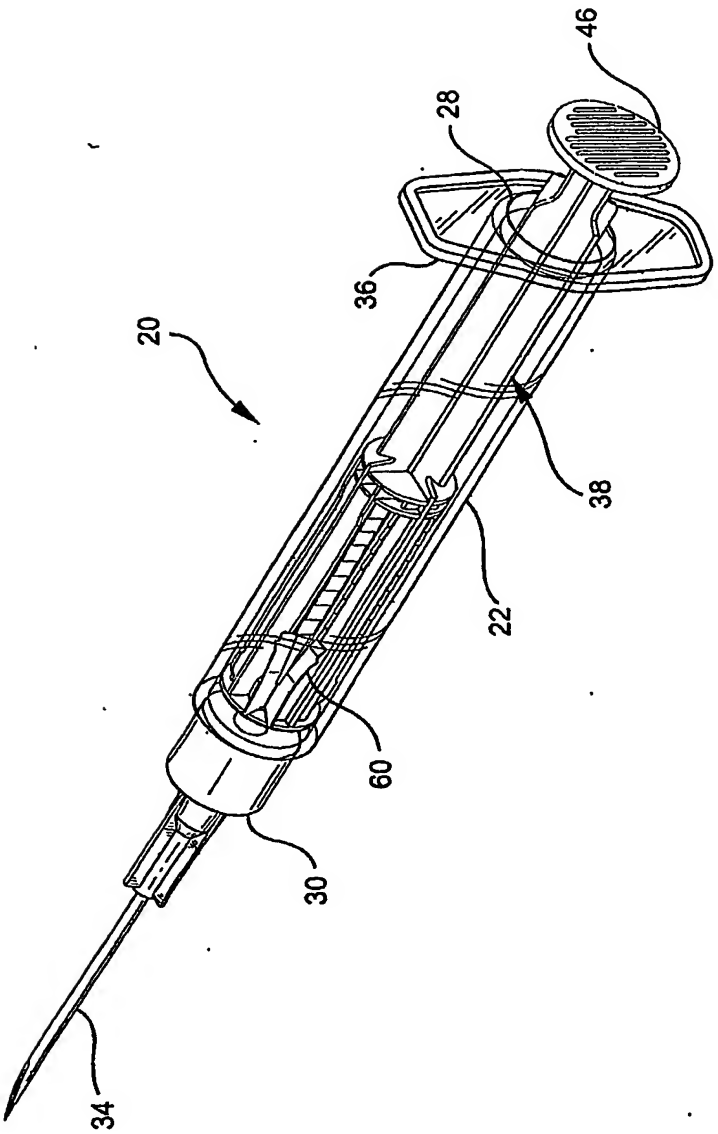

FIG. 4

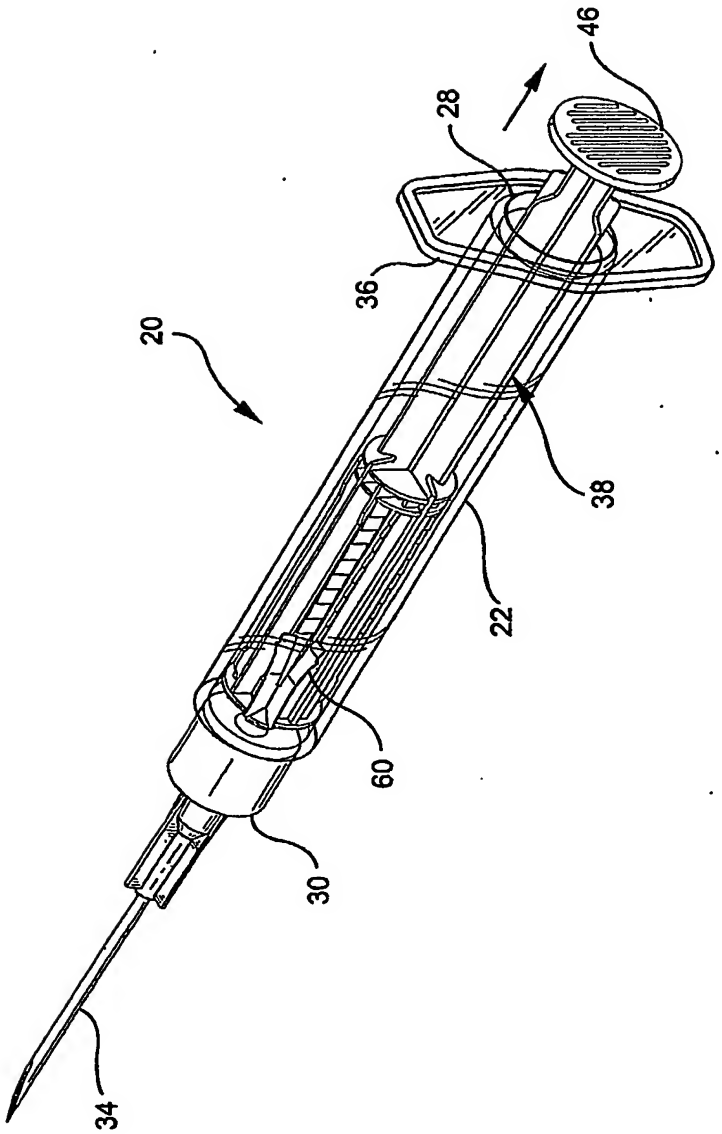

FIG. 5

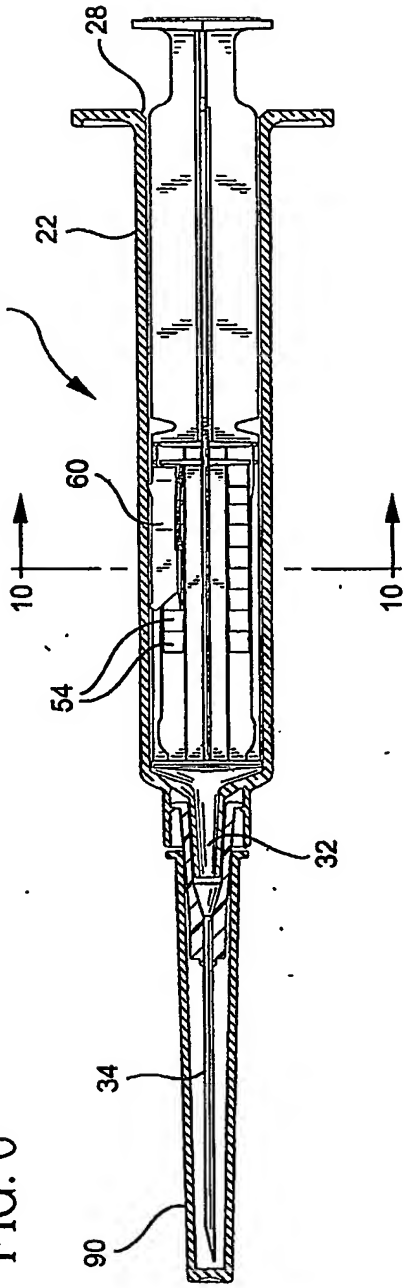

FIG. 6

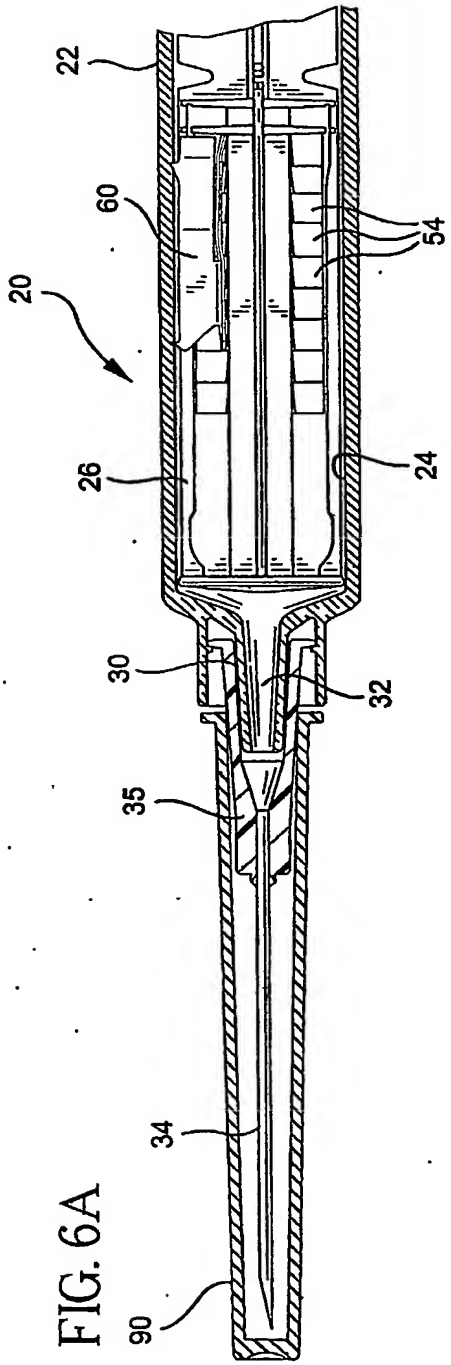

FIG. 6A

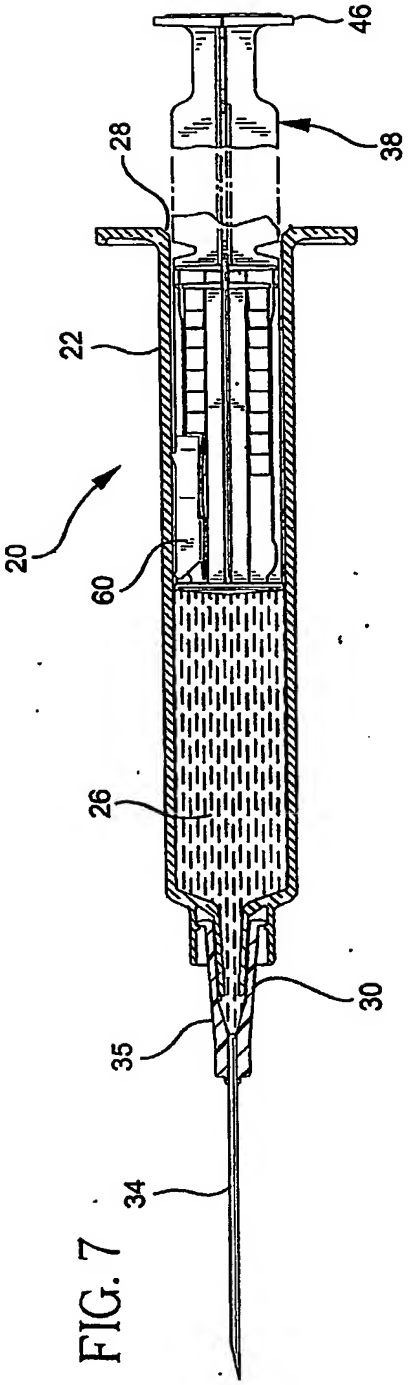

FIG. 7

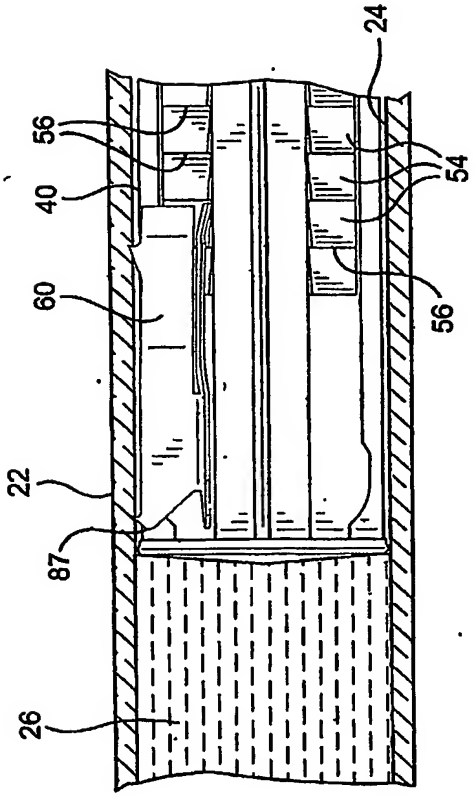

FIG. 7A

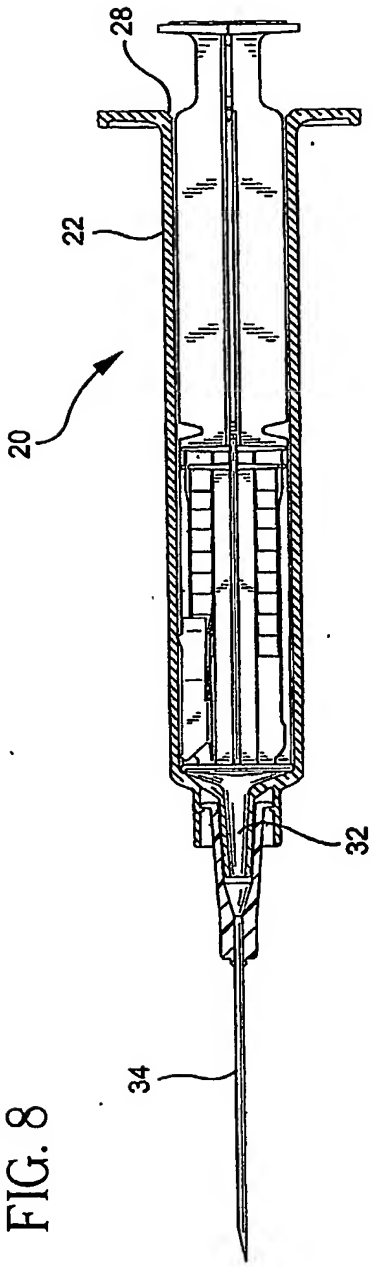

FIG. 8

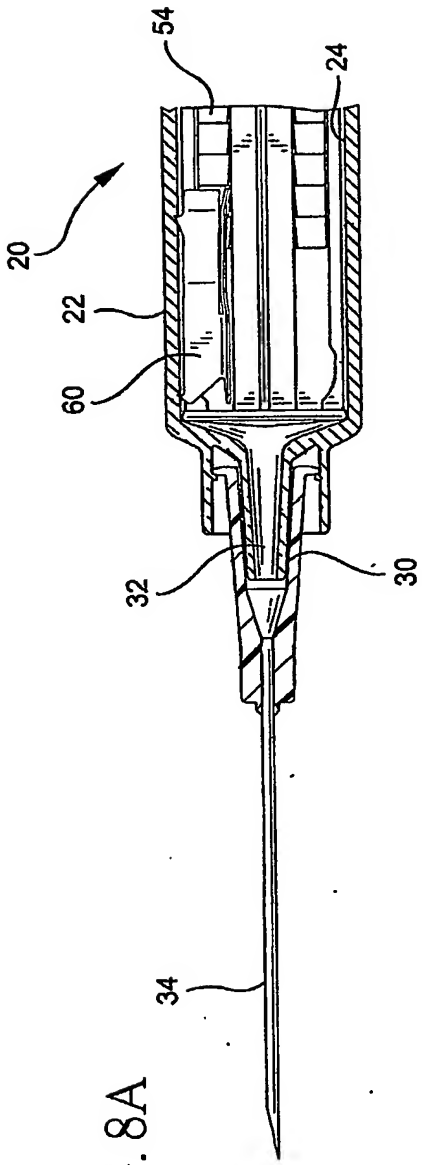

FIG. 8A

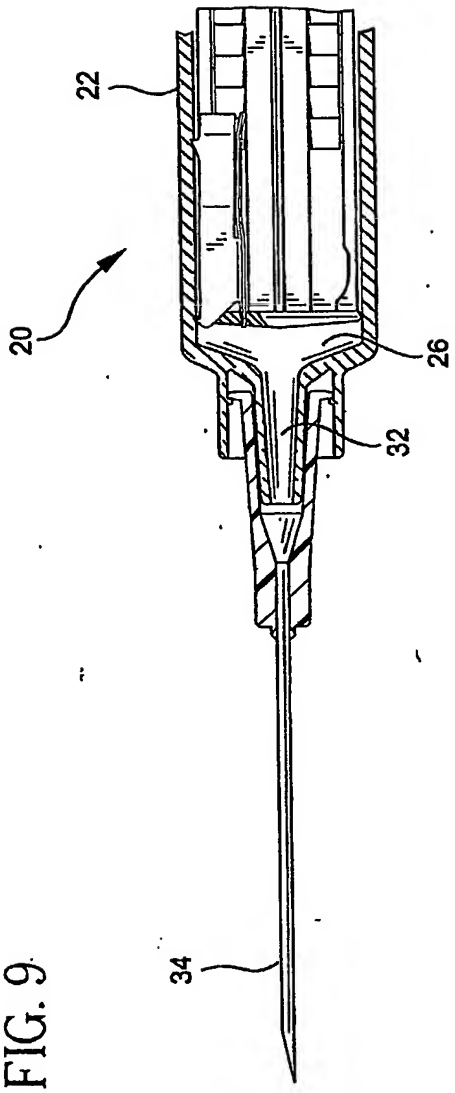

FIG. 9

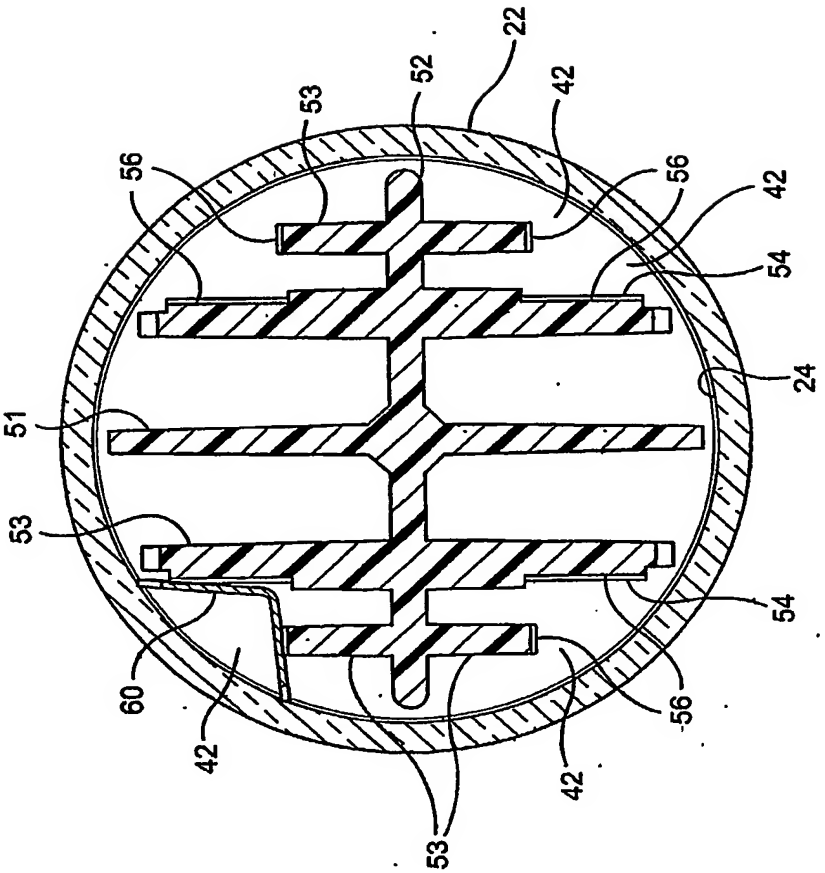

FIG. 10

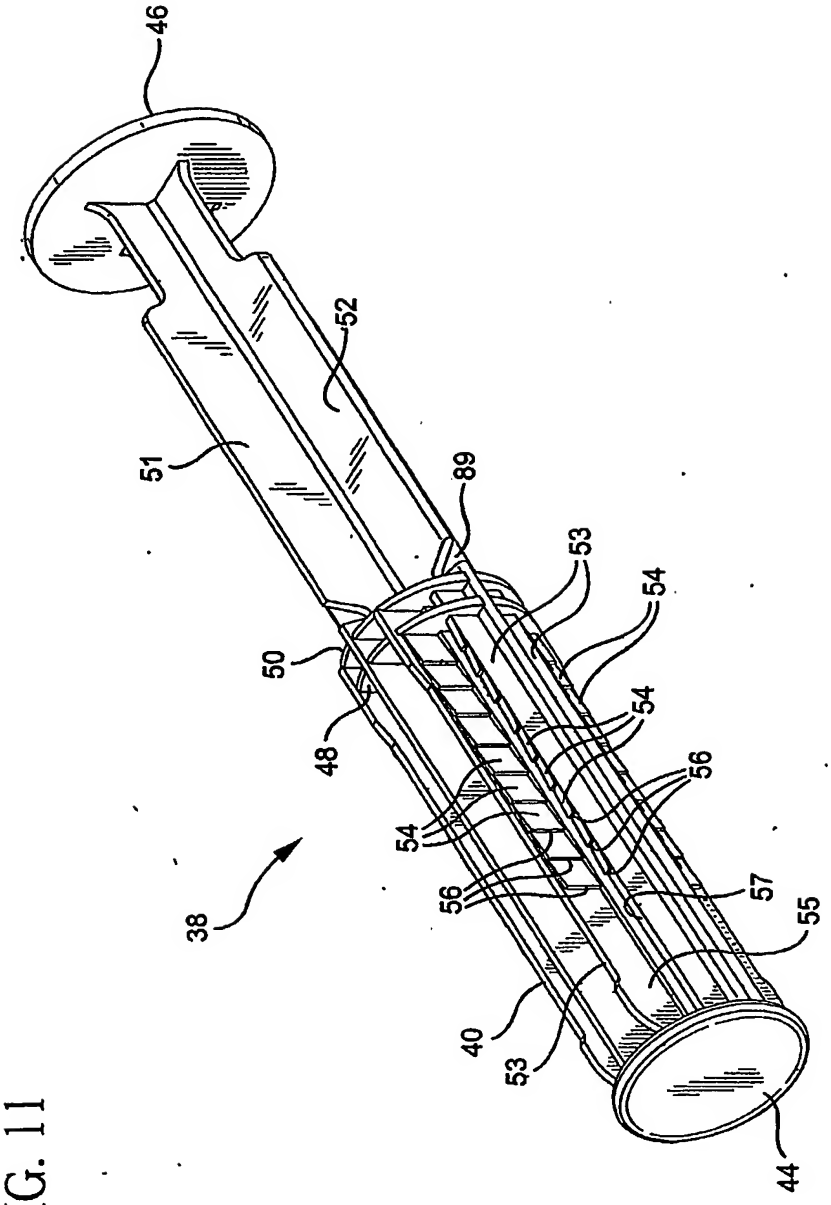

FIG. 11

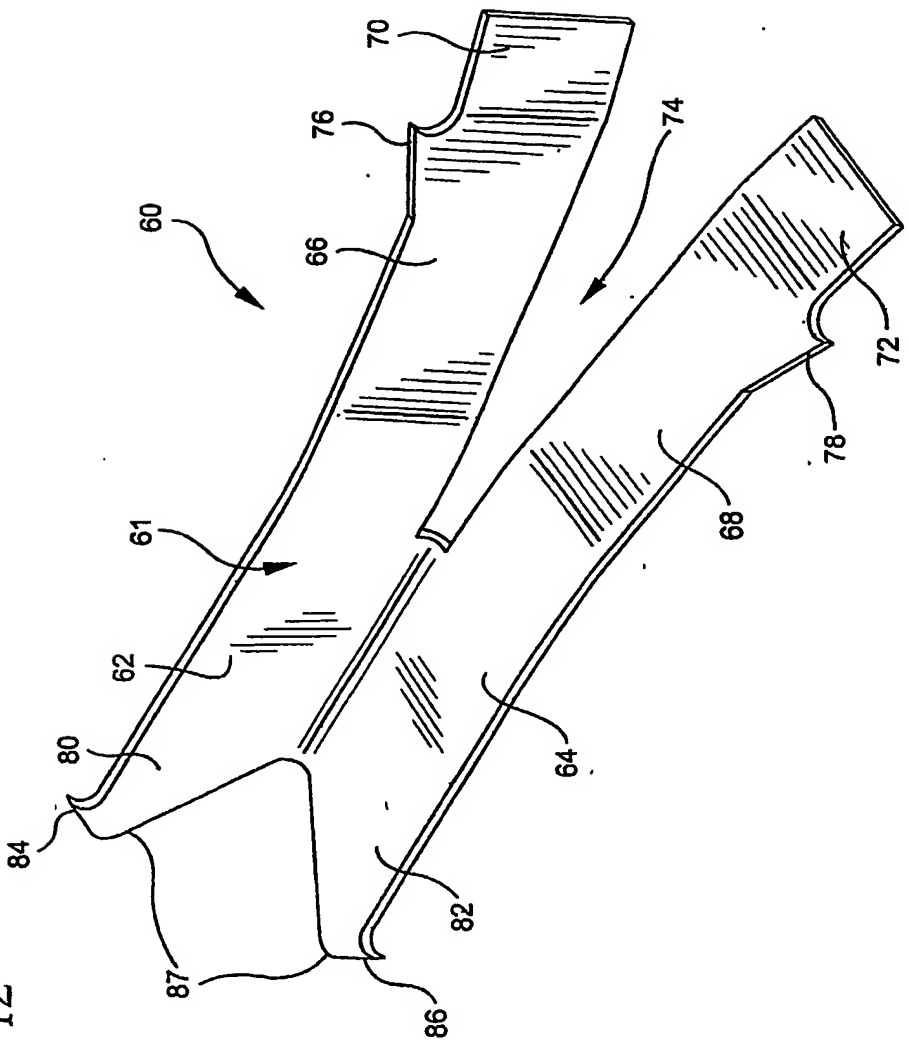

FIG. 12

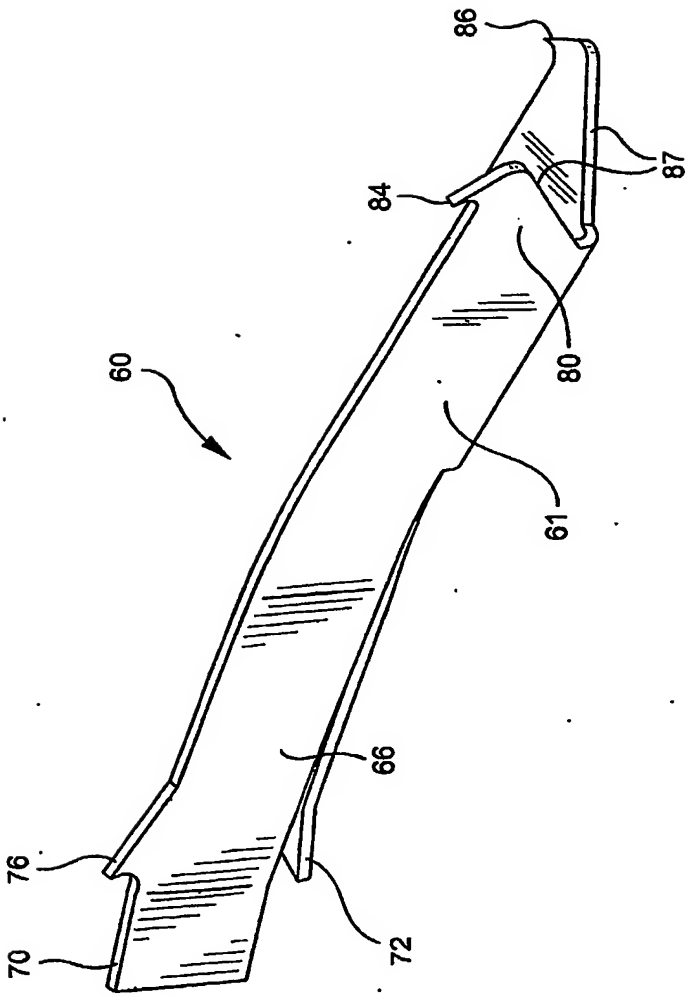

FIG. 13

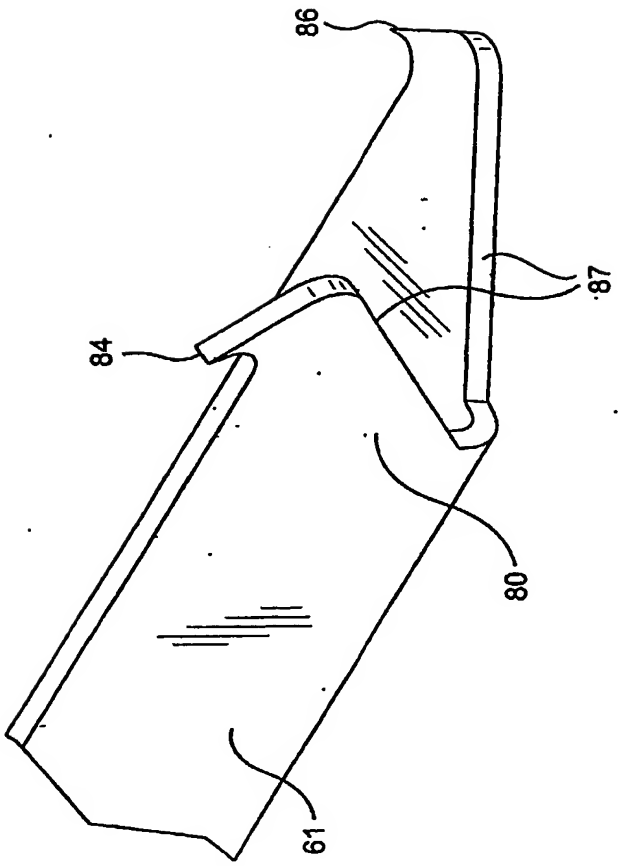

FIG. 14

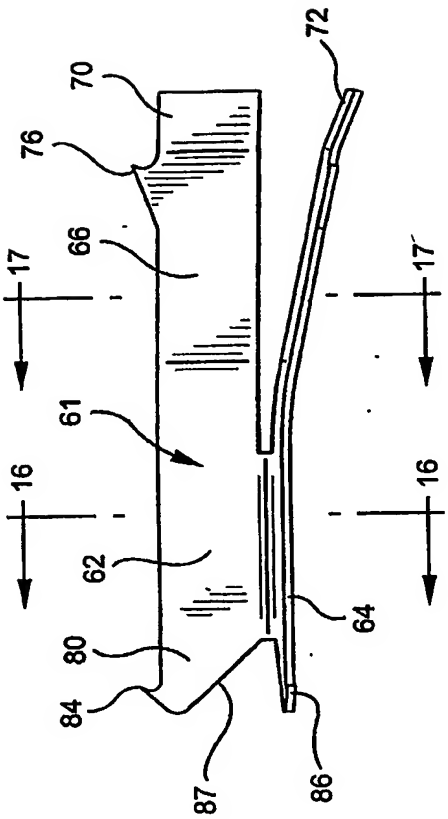

FIG. 15

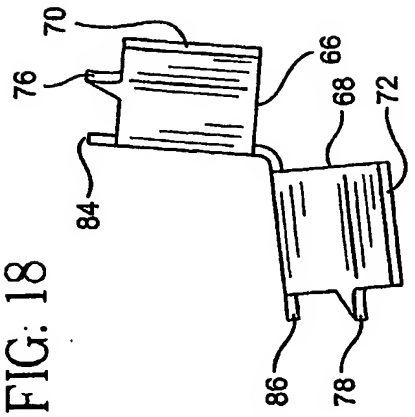

FIG. 18

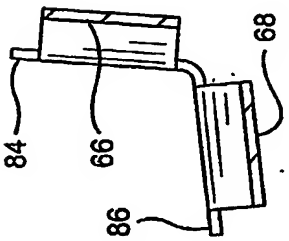

FIG. 17

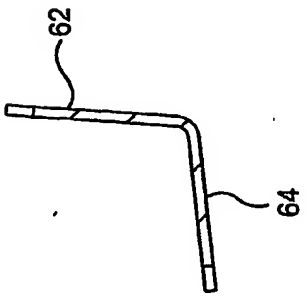

FIG. 16